

ISSUES RELATING TO EPHEDRA-CONTAINING DIETARY SUPPLEMENTS

HEARINGS

BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
AND THE
SUBCOMMITTEE ON
COMMERCE, TRADE, AND CONSUMER PROTECTION
OF THE
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ISSUES RELATING TO EPHEDRA-CONTAINING DIETARY SUPPLEMENTS

WEDNESDAY, JULY 23, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Burr, Bass, Walden, Tauzin (ex officio), Deutsch, DeGette, Davis, Schakowsky, Waxman, Rush, and Dingell (ex officio).

Also present: Representatives Barton and Susan Davis.

Staff present: Alan Slobodin, majority counsel; Mark Paoletta, majority counsel; Casey Hemard, majority counsel; Kelli Andrews, majority counsel; Tom Dilenge, majority counsel; William Carty, legislative clerk; David Nelson, minority investigator and economist; Nicole Kenner, minority research assistant; and Jessica McNiece, minority staff assistant.

Mr. GREENWOOD. Meeting will come to order.

I ask the guests please take seats.

We welcome everyone this morning, particularly our witnesses.

I want to warn you all that we are probably going to be begin votes in something like 15 to 20 minutes, and so we will have disruption. But hopefully after those votes we will have a relatively uninterrupted hearing.

Without objection the subcommittee will proceed pursuant to Committee Rule 4E. So ordered.

The Chair recognizes himself for an opening statement.

Good morning and welcome to the first day of hearings on issues relating to Ephedra-containing dietary supplements.

Baltimore Orioles pitcher Steve Bechler and high school athlete Sean Riggins probably thought they were helping themselves with the ephedra supplements either to lose weight to enhance athletic performance. Tragically, these two young men, 23 years of age and 16 years of age respectively, died. And coroners who investigated their cases believed ephedra played a role in their deaths.

Steve Bechler and Sean Riggins were 2 of an estimated 12 to 17 million Americans who consume more than 3 billion doses of ephedra products every year. With the ephedra reportedly found in more than 200 weight loss aids and energy booster, ephedra based products have grown in popularity in the past decade, especially with athletes and those trying to lose weight quickly.

The millions of Americans who are motivated, some might call it desperate, to lose weight quickly are ideal targets for the marketers of ephedra-containing supplements. They advertise the seductive promise to “lose weight and enhance your energy” simply with a couple of pills everyday. But are these ephedra products safe? Have the risks of these products been assessed and disclosed? These are the general questions of our inquiry today.

Let us begin with what ephedra is. It’s a stimulant derived from the Chinese herb mahuang. The herbal form has been used in China for thousands of years to treat, temporarily, asthma and other respiratory conditions, a major argument with the dietary supplement promoters have used to rebut claims that ephedra is unsafe. Over the past decade these companies, including Metabolife, Cytodyne and NVE Pharmaceuticals, which are represented at this hearing today, have manufactured ephedra-containing products. But it promoted them for different purposes.

Moreover, most of these new age ephedra products contain a dosage combination of ephedrine and caffeine as the primary active ingredients, as well as other active ingredients including stimulants, many of which have not been in use for thousands of years as have the traditional Chinese herbal form.

Ephedra is a complex substance that has placed the Food and Drug Administration in a regulatory quandary. As a botanical, ephedra meets the condition of a dietary supplement regulated under the Dietary Supplement Health and Education Act of 1994, referred to as DSHEA. Under this law dietary supplement manufacturers are not required to prove that their products are safe or effective before introducing them into the market, as drug manufacturers are required to do. Moreover, once the products are on the market, FDA has the burden of proving that a product is not safe in order to take regulatory action.

But ephedra also contains ephedrine as its principle active ingredient. And synthetic ephedrine and other ephedrine alkaloids are regulated as drugs. Synthetic ephedrine is available over the counter and in some prescription drugs but is not offered in combination with caffeine or other stimulants. And there are no synthetic ephedrine products approved for long term use.

The result of this legal and regulatory framework is that dietary supplements containing ephedrine-caffeine combinations are widely available and subject to less regulation than drugs that contain ephedrine which are not permitted to have ephedrine-stimulant combinations. Does this make any sense?

Ephedra has been linked to serious side effects, including stroke, seizure, heart attack and death. In 1997 the FDA attempted to restrict access to ephedra significantly based on adverse event reports. In April 1999 internal FDA memo about the agency’s in-depth analysis of 18 adverse event reports concluded that “these products may constitute a significant public health hazard.” Similarly, a March 2000 internal FDA memo concluded that “the most plausible and likely interpretation” is that there is “is causative association between ephedra supplements and the cardiovascular and central nervous system adverse events reviews.”

As of September 27, 2002 FDA had received approximately 1800 adverse event reports related to ephedrine. But this may not be

representative of the true number of adverse events associated with ephedrine. FDA has estimated that it receives reports for less than 1 percent of the adverse events related to dietary supplements, and just last summer Metabolife released information on nearly 15,000 adverse event reports they had received since 1997 concerning its ephedra containing product Metabolife 356.

Now this last fact is particularly disturbing, given that Metabolife had represented to FDA that it had “never received one notice from a consumer of any serious adverse event which has been asserted to be associated with the ingestion of Metabolife 356.”

In response to a recent Rand Corporation report which provided additional analysis of safety concerns that may be associated with ephedra-containing supplements, the Department of Health and Human Services began regulatory proceedings to increase protections for consumers. And for the first time issued a statement cautioning the public about the use of ephedra-containing supplements, particular in combination with strenuous exercise or other stimulants. And one expert recently hired by FDA to review industry sponsored safety data recommended that ephedra be made available only by prescription.

The foregoing should suggest that we must take company representations with more than a grain of salt. Ephedra promoted as a seemingly safe thousand year old traditional Chinese medicine is no such thing. There is a difference between the product and its uses in China as compared to this country, as already mentioned. Indeed, the expert information provided by China’s State Drug Administration seems to indicate that higher dose ephedra is sent to the U.S. and lower dose ephedra is provided to the Chinese market. FDA inspection of one Chinese ephedra manufacturer showed that the ephedra intended for the United States had been spiked with additional natural ephedra extract to increase its potency.

Ephedra companies also have toted various studies to support claims of proven safety. However, on close examination serious questions have been raised about the conduct and the results of these studies we will inquire about today. For example, certain emails we have uncovered appear to indicate that one ephedra company was trying to influence the work of one of its researchers to make the study more marketable. Yet another ephedra company has told the committee it has never tested the safety or efficacy of any of its roughly 80 ephedra-containing products. In fact, we have learned that after the company pulled one product off the market, at the time of the controversy over the death of Sean Riggins, its president, a high school graduate with no medical training, decided to change the formulation of the product by increasing the amount of the ephedrine and changing the name without consulting any scientific or health experts.

We also must question the industry claim that most adverse side effects associated with ephedra occur when people do not use the supplements according to the manufacturer’s direction. A GAO analysis of internal adverse event reports from one such manufacturer, which was conducted at our request and will be released at this hearing today, found that amount the subset of claims in which adequate usage and dosage information was provided by the

consumer, the consumer was following the manufacturer's recommended guidelines the vast majority of the time.

This morning we will hear from two families who have witnessed firsthand the risks associated with ephedra. We will hear from Steve Bechler's mother and father and from Sean Riggins' dad. And let me thank you all for coming here today to share with us your tragic and personal experiences.

On the first panel we also will hear from Michael Vasquez, a nurse who worked for Metabolife in 1999 and who will discuss how the company handled complaints of serious adverse health events.

We also are fortunate to have five independent experts on issues relating to ephedra safety.

Our second panel will be appearing before us only briefly. Michael Ellis, David Brown and Daniel Rodriguez all of Metabolife, have appeared before us this morning pursuant to subpoena. All three are expected to assert their constitutional right against self-incrimination and will not provide any evidence or testimony to the subcommittee today.

On our third panel will be representatives of 3 companies that manufacture ephedrine-containing products; Metabolife, Cytodyne and NVE Pharmaceuticals. Joining the companies will be 2 scientists who have performed research on Cytodyne and Metabolife's products.

I would like to thank all of our witnesses for attending.

And now recognize the ranking member of the subcommittee, Mr. Deutsch for his opening statement.

Mr. DEUTSCH. Mr. Chairman, I'd like to yield to the ranking Democrat of the full committee to make his opening statement.

Mr. GREENWOOD. The Chair recognizes the ranking member, Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank the distinguished ranking member of the subcommittee for his courtesy to me. And I am very appreciative.

I thank you also, Mr. Chairman, for convening these 2 days of hearings on a very important topic: The failure of the United States to properly regulate the use of the herbal form of a stimulate drug that has caused death and other serious health problems. I repeat, it kills.

It is available in the United States not only as a drug, but as a dietary supplement called ephedra. We shall see today how unscrupulous operators with disdain for public health consequences of their actions have bent, broken or otherwise abused a law which is too weak to sell products that can and do kill and seriously injured the uninformed user.

Further, they have made claims in their advertising that attract those who are extremely vulnerable; young people hoping to make their high school sports teams or overweight persons hoping to lose pounds without adopting healthy diets or regular exercise.

There are some in the industry that would have us accept the notion that ephedra is only an outlier. That the law is sound and only this single substance needs to be banned. I do not believe that that is the truth, and I believe they know better.

I believe that these hearings will reveal that it is because of a combination of weak language in a statute which was passed in a

burst of unwisdom in the U.S. Senate, clever uncovering and use of legal loopholes, and, shoddy and poorly funded enforcement that the law cannot be used to adequately protect the public from these modern day patent medicine peddlers and snake oil salesmen. Given the state of law, at least as currently interpreted, there is simply no way that even educated consumers can distinguish between dietary supplements that can provide real benefit at an affordable price and often dangerous rip-offs that have become pervasive, at least amongst the heavily advertised products of this industry. I will point out that this industry is full of shysters, they are not properly required to label the products or to be regulated as to either safety, efficacy or the quality of manufacturing practices.

I hope that these hearings and others will come to provide us with information needed to reform the underlying statute on a bipartisan basis. Frankly, this is one of the shameful statutes on the books which does not protect the American people and scoundrels are enriching themselves by this device. American consumers deserve to be able to get vitamins and other supplements that will enhance their lives without falling prey to charlatans and scoundrels that promise the impossible but not only deliver disappointment at best, but disaster at worst.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman for his statement and now recognizes the Chairman of the Full Committee, the gentleman from Louisiana, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Today's hearing represents a continuation of the incredibly work the subcommittee has done on behalf of the American people. And I want to thank all of you on the subcommittee on both sides of the aisle for that.

You have helped protect consumers. You have helped protect investors and parents concerned about the safety of their children.

We are here today to shine the light, the spotlight of congressional inquiry on what is truly a life and death issue; the safety of ephedra-containing dietary supplements. These supplements marketed and used to spur weight loss or increase athletic or sexual performance and can be bought in any 7-Eleven, any convenience store or gas station by anyone including those under 18.

The issue for today's hearing is whether continuation of such a policy for ephedra makes sense, given what we have learned about the dangers of ephedra.

It also, I believe, shines a spotlight on the debate we will have the floor tomorrow on the FDA's role in protecting the safety and efficacy of drugs under FDA regulation in our society. Some will be asking us tomorrow to vote to allow importation of drugs from other countries without FDA certification of safety. I think today we will learn the dangers of that kind of a policy.

Under current Federal law companies that make and market these supplements do not have to test the safety of their products, nor do they have to prove that they work as advertised. The 1994 Congress passed a law that restricted FDA's regulation of these products on a theory, the theory that dietary supplements are more akin to food products than actual drugs. That might have made sense then and remains a sensible approach for the vast majority

of dietary supplements. But with this regulatory leniency comes a heavy dose of corporate responsibility and accountability, and one which based upon this committee's investigation to date appears to have been willfully ignored by ephedra manufacturers.

We learned that these ephedra supplement makers have been engaged in some highly questionable behavior—from producing products without any safety testing, to promoting safety and efficacy based on dubious industry-sponsored studies; from making changes to their products to increase doses of stimulants without any kind of scientific or health review, all the way to hiding thousands of consumer health complaints from regulatory authorities. Such conduct is simply unacceptable.

The argument that the Federal Government does not yet require these companies to act any differently is not excuse for their blatant disregard for health and safety of their consumers. If they do not clean up their act, I can promise we will do it for them.

I know that the FDA has authority to take action against dietary supplements if there is evidence of safety problems. It certainly seems to me that in the past the agency has failed to confront aggressively enough this growing problem. I am extremely pleased that Secretary of Health, Secretary Thompson and our Administrator of the FDA Dr. McCellan have taken a much more proactive and aggressive approach to dealing with the dangers of ephedra. And I am anxious today to hear the witnesses, particularly those of you who had personal losses as a result of, I think, the abuses of this particular product.

Let me say again, we created our FDA. We created it with the authority to investigate and to make certain that the drugs that are used in our society are used in a safe manner. That they are safe drugs. That their efficacy is tested. And that the people who manufacture them and sell them in this country always—always operate their business and produce their products with safety in mind. That appears not to be the case with ephedra, and that appears to be a reason why this Congress needs to take a much more aggressive position when it comes to this particular product.

And I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes, again, the ranking member from Florida, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman.

And thank you for having this hearing, but also thank the witnesses for being here. I appreciate particularly the witness who have had family members who have been lost.

We are doing our job today as the Oversight and Investigation Subcommittee of the Commerce Committee, in that we are the people that are the elected representative overseeing the FDA. And when the FDA fails, it is our responsibility.

I look forward to the testimony, not just from the family members, but from the medical people and industry people. Clearly there is an issue in terms of what has happened and, obviously, it is our job to try to prevent that from every happening to another family in America.

And I look forward to the witnesses.

Thank you, Mr. Chair.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from Oregon, Mr. Walden.

Mr. WALDEN. Well, thank you very much, Mr. Chairman.

I want to thank you and your staff for working with me over the past several months to shine some light on the safety of dietary supplements that contain ephedra.

If you had asked me a year ago about ephedra, I would have had to admit that I was not very familiar with it. I suspect that many of my constituents, probably Ernie and Pat Bechler, would have said the same thing.

I would like to welcome the Bechlers and thank them for traveling thousands of miles to be with us today. I make that trip back and forth to Oregon every week, so I realize the sacrifice they have had to make to be with us.

I also want to extend my sincere condolences to them and the other members of their family on the loss of their son, Steve.

A lot has changed in a year. On February 17, 2003 I opened the sports section of the Medford Mail Tribune and read the terrible news that Steve Bechler, a young man from Medford, Oregon, my district, whose talent brought him all the way to spring training camp of the Baltimore Orioles, had collapsed during field drills and was being treated in a Florida hospital. News broke later that day that Steve died as a result of multiple organ failure.

The Broward County Medical Examiner indicated that the dietary supplement Xenadrine RFA-1, similar to this, which contains the herbal supplement ephedra might have contributed to Steve's death.

Since learning about ephedra in such a disturbing way, I was shocked to discover that anyone of any age can walk into a store anywhere in our country and purchase dietary supplements off the shelf that contain the same substance that played a role in Steve Bechler's death, and that of others.

Nowhere on the label of these supplements is a little black warning box or the statement that says may cause death. I am particularly troubled that middle school and high school athletes, teenagers, not only have access to a substance that has been called into question and linked to so many serious health complications, but daily are bombarded by advertisements telling them how this is the miracle way, this is the easy way to lose weight, this is the simple way to get strong; all the other things that go with some of the advertising that some courts have ruled to be misleading.

Unfortunately, the Food and Drug Administration must sit and wait for tragedies to occur since dietary supplements such as Xenadrine RFA-1 can be marketed and sold without FDA approval. For such products FDA must prove the supplement is unsafe and causes harm before it can be removed from the market. The burden of proof to verify that the supplement is hazardous rests with the FDA rather than with the supplement manufacturer. Yet manufacturers of dietary supplements are not required by law to provide reports of adverse events to the FDA. Therefore, at best, FDA has a dull set of instruments to work with including voluntary post-marketing reporting of adverse events, data from poison control centers, reports and inquiries from consumers and health care providers and complaints from trade competitors to better understand

the safety of dietary supplements and to track potentially dangerous supplements. I truly fear that this passive system may be placing unsuspecting consumers at high risk.

For these reasons, my colleague from New York John Sweeney and I introduced H.R. 1075, the Ephedra Public Protection Act legislation that shifts the burden of proof from the FDA to the dietary supplement manufacturer to demonstrate that products containing ephedra are safe prior to such supplements entering the marketplace. I am hopeful the full committee will consider this legislation in the coming months.

Mr. Chairman, thank you again for your dedication to this issue and to ensuring the safety of all consumers. I look forward to the testimony of our witnesses, and I am optimistic that this hearing and the one tomorrow will move us closer to effectively addressing and mitigating the risk posed by dietary supplements that contain ephedra.

Mr. GREENWOOD. The Chair thanks the gentleman, and thanks him for his good work on this issue.

The gentlelady from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

And before making my statement, I would like to recognize a colleague from California, Ms. Davis, who is joining us not on this committee, but who has been a leader both in the California in the legislature and also here in the U.S. Congress in attempts to regulate ephedra.

Mr. GREENWOOD. The Chair welcomes her participation.

Ms. DEGETTE. Thanks.

Today's hearing addresses a topic that I know concerns all of us, which is the potential dangers of the dietary supplement ephedra and the extent to which this is being marketed to unsuspecting customers.

Ephedra is a potent plant product, both the herbal and chemical formulations of this drug are precursors for methamphetamine, a powerful stimulant that is infamous as a drug of abuse. And as we have heard today, it is also billed as a weight loss supplement. Often times people think because something is herbal, it is not harmful. But as we are learning so tragically, that is not true.

I am interested in learning more from the numerous critical experts on our panels today, and I want to thank the Chairman for calling those experts. I think they will be very helpful in understanding the extent of this issue.

Also, we will explore the effects of the Dietary Supplement Health Education Act, which was passed in 1994. And, frankly, there are many, many questions about its efficacy that have arise since then.

Some say that the law has allowed buyer beware to replace safe and effective when used as directed. I am concerned that consumers are not given enough understandable information under this law. Some of the witnesses on today's panel believe only a physician can make an informed decision on the use of ephedra. Other witnesses will argue the opposite. This is an important debate and I look forward to hearing all perspectives on it, with the bottom line being it is our job as Members of Congress to protect our constituents and the unsuspecting public.

Ephedrine and caffeine combinations are illegal when sold as a drug, for example, but not when packaged as a supplement. I am hoping to hear more testimony today on the soundness of that policy.

In addition to the questions about the science that is informing the discussion of ephedra and the legislation that regulates it, I am also concerned that magazine and Internet advertising is purposely aimed at the gullible, like young people who have heard so much about hoping to improve their athletic performance or overweight individual hoping that a pill will work better than their last diet.

Tomorrow we will hear testimony from the FDA and the FTC. Their insight and assistance is invaluable, but frankly we do not have much more time to sit around waiting for something to happen to resolve the current regulatory confusion.

I believe the committee has a responsibility to listen and consider the lessons of this 2 day hearing, and I look forward to hearing all of our witness.

And, again, I would like to thank the Bechlers and Mr. Riggins for coming today, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady who yields back the balance of her time.

And recognizes the gentleman from New Hampshire, Mr. Bass, for his opening statement.

Mr. BASS. Thank you very much, Mr. Chairman. I appreciate your holding this hearing. I will be very brief. Obviously, this is a very disturbing issue, it has ramifications not only for an analysis of the regulatory structure surrounding the control and use of dietary supplements, but also the types of recommendations that we might be able to make so that this committee can take some action quickly to protect Americans, American consumers in instances where they may unknowingly be putting their lives in danger.

I think that this is a hearing that is way overdue. I am glad the Chairman put it together, and I look forward to hearing the testimony of the witnesses.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentlelady from Chicago, Ms. Schakowsky for an opening statement.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I am glad that we are going to have an opportunity over the next 2 days to hear about the harmful effects of ephedra or how it has impacted the American public, and what can be done to prevent future injuries and death.

I hope we will act quickly making the necessary changes to keep this often harmful product out of the hands who face such enormous risks from it.

I thank our witnesses for coming today to share with us how ephedra had effected their lives. It's terrible that lives, often very young lives, have been lost because an industry has been allowed to sell and market a product that is both unregulated and known to have potentially lethal consequences. Of course, I particularly want to thank Mr. Riggins from my home State of Illinois, and the Bechlers who have suffered a terrible, terrible tragedy and now are committed to educating the public about the grave dangers that ephedra poses. And I thank you so very much for doing that.

Those of us in Congress and in the public need to hear your stories. We also need to keep in mind that you're representing countless numbers of people who have also been tragically affected by dietary supplements. The bottom line is when used as a dietary supplement, ephedra does more harm than good and it should be removed from the market.

On May 25, 2003 Illinois Governor Rod Blagojevich, a former member of this body, took the bold step of banning the sale of ephedra throughout Illinois. Illinois is currently the only State to ban the sale of this dietary supplement. I support that ban and believe now that we need a national solution. As long as ephedra sits on convenient store shelves in every other State, consumers will continue to assume the product is safe and does not pose a real risk. Dieters will continue to use it lose weight, athletes will use it to improve their game and truck drivers and students alike will use it to stay awake. Unfortunately, some of them will die from using ephedra as well.

Supplements are not held to the same standard as prescriptions and over-the-counter drugs. These manufacturers do not have to prove that their products are safe or effective. The lack of regulation means that consumers cannot be sure how much ephedra these supplements accurately contain. We know concentration can vary from dose to dose, or whether they contain other compounds with possible health effects.

What we know about ephedra is bad enough, but there is also much about ephedra we do not know. We do not know how many people have had their lives ended or their health ruined by ephedra. We cannot be sure what ingredients are contained in the pills, the amounts used or if the ingredients are consistent throughout product. We do not know how the supplements are products. They can and have been manufactured in bathtubs, basements and garages. The lack of transparency afforded to the supplement industry is unacceptable. Consumers should have the ability to make informed decisions about what they choose to put in their bodies. We owe it to the victims and their families to take this supplement off the shelves before anymore unsuspecting consumers, before anymore of our children fall victim to the harmful effects of ephedra and the predatory marketing of this industry.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognizes the gentleman from California, Mr. Waxman for his opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for holding this hearing. It is important that we examine the question of ephedra and the harm it is doing to Americans who are taking this medication without any understanding that it could be doing them an enormous amount of harm. And I thank the witnesses for being here today.

In 1994 Congress passed a law called the Dietary Supplement Health and Education Act, or DSHEA, and the hope was that this law would ensure that consumers had access to dietary supplements that could improve health, such as calcium and folic acid. The law largely deregulated the business of dietary supplements. And over the years it has become clear that one unintended con-

sequence of that law has been that consumers are inadequately protected from potentially dangerous supplements. The subject of today's hearing, ephedra, is the best example, but not the only one, of how this law fails consumers.

Evidence has mounted about the harm from ephedra. Medical organizations have been weighing in from the AMA, the American Heart Association, the American Academy of Family Physicians. They have called on the FDA to prohibit the sale of ephedra as a dietary supplement because of the unreasonable risk associated with these products. Now the FDA says, however, that they think the law ties their hands. I do not agree with them in their interpretation of the law. I think there is enough harm that has been shown from ephedra for them to act. But what we are left with is a product for which there is no evidence of long term positive health outcomes and increasing evidence of various serious side effects. And FDA has not taken the product off the market.

It is time to change this law so that a body count does not have to be amassed before FDA can take a dangerous product off the market.

And I want to pay tribute to my colleague Representative Susan Davis. She has been a leader in this issue in the California legislature and here now that she is in Washington. She and I are planning to introduce legislation that will give FDA greater access to information to understand that the product does pose a health risk and that will let FDA protect consumers from unsafe products.

It is all too possible that there is another ephedra already on store shelves, a product that can cause serious injury that has no demonstrable long term health benefit. We must not let the ephedra story repeat itself.

I am pleased that we are holding this hearing. I look forward to the testimony of the witnesses. And I hope it will help us legislate in the way that we need to protect the American people.

Mr. GREENWOOD. The Chair thanks the gentleman.

And now with unanimous consent permit all of the members of the subcommittee to have their opening statements entered into the record, as well as a written statement from the American College of Obstetricians and Gynecologists.

We are now going to recess. I am hoping that we can be back here close to 11. I cannot promise that because funny things happen when we get on the floor of the House of Representatives. But we will recess until the end of this series of votes.

[Brief recess.]

Mr. GREENWOOD. The committee will come to order.

And the Chair thanks all of our witnesses, again, and all those others in attendance for bearing with us.

And the Chair recognizes the gentleman from Illinois, Mr. Rush for his opening statement.

Mr. RUSH. Thank you, Mr. Chairman.

Mr. Chairman, I am pleased that we are holding this hearing today so that we can begin to come to some clarity on the role that the industry played when it may have mischaracterized the ill-effects of the dietary supplements that contain ephedra. Ephedra based products have grown in popularity in the last decade, especially with athletes and those who are trying to lose weight quickly.

Twelve to 17 million Americans consume more than 3 billion serving of ephedra products every year. This is precisely why we must investigate this issue. There are too many consumers who could be adversely effected by this herb.

We have all seen the reports of deaths that have been associated with products that contain ephedra. We know that the Orioles pitcher Steve Bechler collapsed on a practice field while attending spring training. His teammates reported that they saw Bechler take a dietary supplement that contained ephedra. You may hear reports that the links between his death and the supplement are not conclusive. So if the reports are not conclusive, then there needs to be an investigation.

Mr. Chairman, we should let the facts speak for themselves. If there is nothing wrong with these products, then the investigation should go smoothly. However, I have a strong feel that this investigation will not go smoothly because the evidence they may demonstrate that these products can be linked to serious side effects, including seizure, stroke and heart attack and most critically, death.

The American Medical Association and the American Heart Associations have both called for a ban on ephedra based products, and my own State of Illinois has banned the sale of ephedra. Our military has also weighed in. They have ordered that these products be removed from all stores on military bases worldwide.

It is clear that the panelists who represent the manufacturers of ephedra based products have a lot of evidence to overcome.

Mr. Chairman, I want to thank you for your leadership on this particular issue, and I want to commend you for this outstanding hearing.

And I yield back the balance of my time.

Mr. GREENWOOD. Are there any other members who wish to make opening statements? That being the case, the Chair calls the first panel. Our witnesses are: Mr. and Mrs. Ernie Bechler of San Diego, California; and from Medford Oregon Mr. Kevin Riggins of the Sean Riggins Foundation for Substance-Free Schools; Mr. Michael Vasquez of the law offices of Fred G. Cohen; Dr. Steven Hymnsfield, M.D., Deputy Director of Obesity Research Center of St. Luke's Roosevelt Hospital in New York; Dr. Raymond Woosley, M.D., Ph.D., Vice President for Health Sciences, Arizona Health Sciences Center; Dr. Douglas Zipes, M.D., Distinguished Professor of Medicine, Pharmacology and Toxicology, Director of the Division of Cardiology at Krannert Institute of Cardiology, which is in Indiana; Dr. Cynthia Culmo, a former official with the Texas Department of Health; Dr. Marcia Crosse, Acting Director, Health Care-Public Health and Science Issues at the U.S. General Accounting Office.

We welcome all of our witnesses. I believe you have been informed that pursuant to the rules of this committee, we take our testimony during investigative hearings under oath. And so I need to ask if any of you object to giving your testimony under oath?

Seeing no such objection, I would inform you that also pursuant to our rules, your entitled to be represented by counsel. Do any of you wish to be represented by counsel?

Mr. and Mrs. Bechler, you do. And if you would identify your counsel to your right, Mr. Bechler? And if you would identify yourself, sir, using the microphone and making sure it is on.

Mr. FRANCE. Jim France on behalf of Mr. and Mrs. Bechler.

Mr. GREENWOOD. Okay. I would then ask the witnesses to stand and raise your right hands, please.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are all under oath.

And I believe we are going to begin with the Bechlers. Again, welcome. Thank you for being with us this morning, and you are recognized to give your testimony. And you will need to use—which one is going to start testifying. Mrs. Bechler, Mom's going to do that. Okay.

TESTIMONY OF PAT BECHLER; KEVIN RIGGINS, SEAN RIGGINS FOUNDATION FOR SUBSTANCE-FREE SCHOOLS; MICHAEL VASQUEZ, LAW OFFICES OF FRED G. COHEN; STEVEN B. HYMSFIELD, DEPUTY DIRECTOR OF OBESITY RESEARCH CENTER, ST. LUKE'S ROOSEVELT HOSPITAL; RAYMOND WOOSLEY, VICE PRESIDENT FOR HEALTH SCIENCES, ARIZONA HEALTH SCIENCES CENTER; DOUGLAS P. ZIPES, DISTINGUISHED PROFESSOR OF MEDICINE, PHARMACOLOGY AND TOXICOLOGY, DIRECTOR, DIVISION OF CARDIOLOGY, KRANNERT INSTITUTE OF CARDIOLOGY; CYNTHIA CULMO, FORMER OFFICIAL, TEXAS DEPARTMENT OF HEALTH; AND MARCIA CROSSE, ACTING DIRECTOR, HEALTH CARE-PUBLIC HEALTH AND SCIENCE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Ms. BECHLER. On February 16, 2003 we got a call from the Baltimore Orioles that Steve had collapsed on the field. He was 23 years old, and he was married for 2 months, had a child on the way, which was born April 22. Now he has a daughter that will never know how great his daddy was, and she will never be with him.

He started baseball at 7 and wanted to work at this Myles Field, which was a big stadium in our town, home town. He said, "Mom, 1 day I am going to play here," and he did. He played Little League, Babe Ruth and was always an All Star. And then he hit the big time and he played big league, and that was shortly lived and was a dream cut short.

I do not know how long Steve was taking this exactly. But the Cytodyne, they have received dozens of complaints from the consumers, some my son's age, complaints of strokes and heart attacks. They ignored these complaints. They knew about all the complaints that were compiled by the FDA. Hundreds of deaths, hundreds of serious injuries, strokes.

They lied to our son about their product being safe. They knew there were questions about its safety. They sponsored clinical studies with the results that it showed problems and questions about Xenadrine. Whether it worried or whether it was safe, they manipulated the results in the study they advertised in claims of its safety. It was an herbal vitamin, a life herb.

They paid researchers and in the companies to distort the facts of whether they were really safe or not. They seduced advertisers and son to take it with the flukes of promises of hopes of dropping

massive weight or muscle mass fast and safe. They lied about the testimonies that stated extreme weight loss, which he was 10 pounds overweight.

The testimony advertised that Cytodyne was a strong and—they took bodies building type people and paid them to fatten and given their multiple products that led my son to believe that he could achieve the huge weight loss and fat loss in a few short weeks.

They took our pride and joy from us, and his wife and his baby. And they took our baby from our lives. Steve was our lives. And his daughter will never know him.

How many Steve Bechlers or Sean Riggins have to die to prove that these are not safe.

They paid—we need to get this off the market. We have got to help other children. They want the extra boost that think they can make them better athletes, and it does not. All it does is encourage kids to take and make it easy for them to take it.

Please, let us get this out of the hands of children.

Thank you.

Mr. GREENWOOD. Thank you, Ms. Bechler. And we know how proud you are of Steve, and I think at this moment he is very proud of you.

Mr. Bechler, did you want to add anything?

Mr. BECHLER. No, sir.

Mr. GREENWOOD. Okay. Well, perhaps you might to respond to some questions later on.

Mr. Riggins, thank you also for being here on behalf of your son and you are recognized.

TESTIMONY OF KEVIN RIGGINS

Mr. RIGGINS. Thank you, Mr. Chairman.

I am here today to represent several people; myself, my wife and a lot of people that have lost children to a dietary supplement called ephedra. I am happy and proud to say that I am also representing the American Heart Association, Midwest affiliate. They have been with us for several months now in our efforts in Illinois, and their President, Dr. Robert Banow, has stated what you all have stated to us; that ephedra is dangerous, it kills and it needs to be off the market.

My son Sean was 16 years old. He's a phenomenal athlete, football player, wrestler, martial artist and yet he and several of his friends on the football team decided that they could get an energy boost to enhance their performance by taking these products that contain ephedra. And on September 3 last year Sean had a heart attack and died in our home. The cause of the heart attack, ephedra.

I do not have to tell you about the dangers of this product. You know that it is a stimulate, you know that it effects the cardiovascular system and the central nervous system.

I do not have to tell you about the Dietary Supplement Health and Education Act. You told us about it. You already know. It allows these companies to put these products out with virtually no regulation and no oversight. The majority of these companies, in my opinion and the opinion of anyone who has gone through what we have gone through, these companies are illegitimate companies.

They are no more than drug pushers because they are marketing a deadly substance and they do not care.

Seventeen and a half billion dollars, that is how much dietary supplement companies made last year as a whole. The claim is that ephedra is only 1 percent of that. I personally do not believe that. I think it is more toward 10 percent or better.

We know it is deadly, we know it kills. In my home State of Illinois our legislators realized that as well, and we passed the Ephedra Prohibition Act unanimously through both Houses: 56 to nothing in the Senate, 117 to nothing in the House. And we had previously spoken to the Governor and he promised that he would sign it when they passed it through the Houses. It went into effect in May, and Illinois became the first State to ban the sale of ephedra products.

And today I come before you and ask you as our Federal legislators to do the same thing. Because we do not know how many people have died. We do not know how many people out there have lost children, such as the Bechlers and ourselves.

Ephedra has been in the dark for years and years and it is this type of forum that we need to bring it out into the light, let people see it for what it really is so that they can be aware that this is not the miracle pill. This is not a magic elixir that will help them lose weight and enhance their performance. It is poison. It killed my son. It killed the Bechler's son. And how many other children do we have to lose before we decide that this is poison and remove it from the market?

Several weeks ago we all celebrated Father's Day. A few weeks before that, Mother's Day. For our family and for several other families—excuse me, a 100 or so other families. Those holidays will never ever be the same again. There is no celebration for us. And I ask you to make sure that no other family has to deal with what the Riggins and the Bechlers and God knows how many other families have had to deal with.

Thank you.

[The prepared statement of Kevin Riggins follows:]

PREPARED STATEMENT OF KEVIN S. RIGGINS, FOUNDER AND DIRECTOR, THE SEAN RIGGINS FOUNDATION FOR SUBSTANCE FREE SCHOOLS

Honorable Representatives, my name is Kevin Riggins. My wife and I live in Lincoln, Illinois. On September 3, 2002, we lived every parent's worst nightmare when our only child, Sean Riggins, died from a heart attack. Sean was a gifted athlete, excelling in football, wrestling and Tae Kwon Do. He had no congenital heart problems and he was in the peak of health. He had just passed his athletic physical examination in order to start football. As we were to find out later, the heart attack had been brought on by the usage of a dietary supplement called ephedra. My wife and I were not familiar with this particular substance; in fact, we had no idea that Sean had been taking it. As we were to discover later through investigation and conversations with Sean's teammates, numerous teenagers, including athletes, and young people trying to lose weight, were using these products. The teens could buy these pills at the corner gas stations with pocket change. The little packages, which promote weight loss, performance and energy enhancement, were being sold right next to the Twinkies and candy bars, in fact, the use of these products was so casual, none of the kids believed that they were taking a drug. With the marketing style and the ease in which they could be obtained, the teens thought nothing of it. "They sell these things in the stores, they are not illegal, so they must be okay". This was a quote from one of my sons friends. As it turns out, the vast majority of the American public believes this as well. As Americans, we believe that our regulatory organizations, in this case the F.D.A., are protecting our interests by not al-

lowing dangerous products to be sold, especially in regards to what we put in our bodies. In the case of ephedra, we could not be more wrong. As you well know, The Dietary Supplement Health and Education Act of 1994, allows dietary supplement companies to operate with virtually no federal oversight. A company does not need a license to produce these products nor are there any no pre-market approval requirements. There have never been any Good Manufacturing Practice guidelines developed for these companies and they have a **voluntary** adverse event reporting system. When a supplement poses a risk of serious injury or death, the burden of proof falls to the Government to prove cause and effect. This is the exact opposite of the rules and regulations set up for drug companies. It is no surprise that the supplement industry wants no changes to be effected in the federal requirements. This is an 18 billion dollar per year industry which does not seem to care that it is producing products that kill. According to the FDA and several medical organizations including the American Heart Association and the American Medical association, ephedra has killed at least 117 persons and accounts for almost 20, 000 serious adverse events. Please bear in mind that these are **reported** adverse events. The supplement companies do not divulge these facts readily or willingly, therefore, we truly do not know how many citizens have been affected by these products. The Poison Control Center recently published a study showing that ephedra is the most dangerous dietary supplement on the market. They used adverse event reports, from the industry, to come to this conclusion. The Ephedra Education Council immediately labeled the study as "garbage". They claimed that utilizing adverse event reports was not a valid way of conducting studies such as this. Conversely, they have touted the Rand Corporations study of ephedra's safety and efficacy as bearing out what they have said all along; that ephedra is safe if used as directed. This, of course, is not true. The Rand study was inconclusive. Ironically, the Rand Corporation utilized the available **adverse event reports** in conducting the study. It seems that the industry only agrees with a study if it agrees with there agenda. The industry claims that there are 55 studies that show the safety and efficacy of ephedra. They bring out physicians, pathologists and other scientists to bolster their claims that ephedra is safe and effective. What they do not say, is that the large portion of these studies are commissioned, financed, supervised and published by the supplement companies, many times using their own people to conduct the studies. The ephedra industry has, unfortunately, become a collection of rogue corporations that care for nothing but the bottom line. Look at the criminal records of some of the CEO's of these companies, and you will see a pattern of criminal activities and corruption. These are the facts, not innuendo, not speculation. Ephedra is a dangerous drug that is being sold as an innocuous weight loss aid and stimulant. Here in Illinois, our general assembly recognized that fact. In November, 2002, I began a campaign to educate our state lawmakers on the dangers of ephedra, and to encourage them to take action. On May 28, 2003, those efforts came to fruition, when after a unanimous yea vote in both house, Gov. Rod Blagojevich signed the Ephedra Prohibition Act making Illinois the first state in the nation to ban ephedra products. Now there are several other states taking up the initiative as well, however, I believe that you, our national leaders, need to take up the cause at the federal level and protect our citizens from this dangerous substance. Labeling requirements are not enough, as we have seen studies that show dosage variations of up to 154% between pills in the same bottle. This makes the dosage requirements listed on the label of no use. Age limitations are not enough; less than ten percent of the adverse events associated with ephedra were attributed to persons under the age of eighteen. The only logical course of action is to remove ephedra from the market completely, and impose stricter regulations on dietary supplement companies to ensure the purity and safety of their products. This is not an issue of trying to stifle business or over-regulating legitimate companies, this is an issue of protecting the American consumers and ensuring the public health. No other family should have to suffer the loss of a child, be that child 16 or 46. My wife and I will never get over the loss of our son, but we can try to make sure that it does not happen again, and to do that, I need your help. Look past the industry rhetoric and all of the misdirection and obfuscation. Help us get ephedra off of the market. The industry will survive and so will our American brothers and sisters. Thank you.

Mr. GREENWOOD. We thank you, Mr. Riggins. We thank you very much.

Our next witness is Mr. Michael Vasquez, and he has patiently waited remotely in San Diego. Can you hear us, Mr. Vasquez?

Mr. VASQUEZ. Yes, sir.

Mr. GREENWOOD. Okay. And I see that you are represented by attorney?

Mr. VASQUEZ. Yes, sir.

Mr. GREENWOOD. And Mr. Attorney, could you identify yourself, please.

Mr. COHEN. Yes. My name is Fred Cohen.

Mr. GREENWOOD. Okay. And we thank you.

Mr. Vasquez, we appreciate your patience and you are now recognized to give your testimony.

TESTIMONY OF MICHAEL VASQUEZ

Mr. VASQUEZ. My name is Michael Vasquez. I am a California licensed registered nurse and public health nurse.

I was employed at Metabolife from August 1999 to November 1999. I had a work related injury at Metabolife in which the case is still pending. I worked as a health information call center staff for Metabolife's Health Information line.

At the time of my employment, I was one of 10 licensed registered nurses that stock the health line. My immediate supervisor was Mr. Daniel Rodriguez. Mr. Dan Rodriguez provided me a 2 day orientation and training for myself and also for another new employee named Linda Rodriguez. We were taught how to answer phones and trained how to take—and document comment, complaints from consumers that were using Metabolife's 356 and other products.

As part of my job description I took a variety of consumer calls in regards to positive comments about Metabolife's 356 such as it's working great for them. Other calls were callers who were frustrated that the product was not working for them. And at times took calls from consumers that were experiencing side effects or as the company would classify it as alleged adverse events.

Complaints from taking the products would vary from abdominal cramps to potential signs in terms of stroke, heart attack, seizures.

I averaged taking 7 to 10 calls a day that were strictly related to alleged adverse effects. Other nurses had a variety of a number of calls regarding alleged adverse events that were reported on any given day.

All the calls were documented and entered into a computer data base in which consumers, if they cooperated, gave personal information such as their name, age, gender, contact phone number and general health status, medical condition if any, description of medications if they were taking any, amount of Metabolife 356 being taken, their eating habits. General complaints of the consumers and what recommendations we nurses were giving out to them.

We received calls from emergency room doctors that wanted to know what ingredients were in the product. And they would request us to fax them an ingredient list because a patient of theirs had either a heart attack, seizures or sometimes death.

We had weekly staff meetings that were attended by Mr. Daniel Rodriguez, who was my immediate supervisor, the medical director Dr. Randy Smith and the other nurses and the chemist. We would talk about the different callers and other health related issues directly related to Metabolife 356 being used.

During our lunch breaks the nurses would compare notes and discuss concerns about the product we received in regards to the different alleged adverse events reported, such as stroke, seizure, heart attack and other severe condition which made us wonder whether the product was safe to take or whether the callers were really telling the truth or not. We nurses had discussions on the actual studies the company claimed to have done and wonder about the validity of it.

At the time I was employed at Metabolife I created a daily, weekly and monthly log which all the nurses had to complete. The logs contained information about how many calls were being answered, emails that were being answered, literature that was sent out and alleged adverse events that were being reported. All of these were being entered into a computer data base.

For consumers that called the health line and reported having moderate to severe alleged adverse events, we were trained and taught to get as much information possible. From then on we had to forward this information to Daniel Rodriguez, which was my supervisor, and then he would take care of follow up on each of those cases.

I am here today on my free will knowing the ramifications that questions may be asked why am I testifying. And after hearing Mr. Bechler and Mrs. Bechler and Mr. Riggins and probably other people out there that are taking ephedra related products, I feel for them.

As a nurse you are supposed to help people and do no harm. But as a human being knowing that product that can and probably is dangerous, I cannot in good conscience condone the use of it.

Thank you, sir.

Mr. GREENWOOD. Thank you, Mr. Vasquez. We thank you very much for coming forward and for joining us as you have today.

Mr. Heymsfield, you are recognized for your statement, sir.

TESTIMONY OF STEVEN B. HEYMSFIELD

Mr. HEYMSFIELD. Thank you.

Mr. GREENWOOD. You need to push the button to turn the microphone on.

Mr. HEYMSFIELD. Thank you.

Following release of the extensive Rand report on March 26 of this year, the Journal of the American Medical Association recommended to the public that the risks of adverse health effects from ephedra products far outweigh the possible minimal benefits. The linkages between ephedra containing products and serious side effects, even death, are now well established. When ingested alone or together with natural sources of caffeine, ephedra alkaloids are potent stimulants that trigger an array of body reactions, some with devastating effects in predisposed individuals.

Almost 100 years ago Samuel Hopkins Adams in a series of articles "The Great American Fraud" decried that gullible America will swallow an appalling amount of opiates and narcotics and a wide assortment of other potent drugs. Hopkins was reacting to the ground swell of contempt for patent medicines that were long on promise, but that failed to disclose the risk of toxic contents. With-

in a year, on June 30, 1906, President Theodore Roosevelt enacted the Food and Drug Act.

Almost two-thirds of Americans are now overweight or obese and many are not only gullible, as in Adams' day, but search in desperation for a treatment. Ephedra products sold in the context of dietary supplements rather than drugs as traditionally regulated by the FDA are viewed by many unwitting consumers as yet one more chance to satisfy their passion for thinness.

In early 1997 my colleagues and I at the New York Obesity Research Center carried out one of the first U.S. controlled clinical trials of mahuang, the botanical source of ephedra alkaloids. I was struck in this pilot study of a commercial product by the stimulant effects observed in ephedra treated patients compared to controls. Heart palpitations, agitation and insomnia, all of which are recognized actions of sympathomimetic agents, as this family of drugs is referred to.

Within the next year I participated with others at our center as a study designer and only physician member in a larger and more rigorous controlled clinical trial of a potent product that contained not only ephedra, but a natural source of the ephedra amplifying factor caffeine. My earlier observations and suppositions were confirmed and extended. Stimulate side effects were present more often in the product treated group and led some patients to drop out or to be dropped from the study prematurely.

The subjects in this study are not representative of the general public because they were medically screened and monitored. Patients with underlying conditions that might pose risk during treatment were excluded from the study.

My original project, formulated now over 6 years ago, has proven to be accurate. When taken by hundreds of thousands of consumers the stimulate effects of ephedra caffeine in combination leads predictably to some pathomimetic adverse side effects in some individuals, serious injuries in others and a small but critically important group death. This leads me to pose the question how could this vicious experiment be carried out on Americans?

I pose here, based on my own experience and opinions, three means by which consumers and regulations were shielded from the growing body of information linking ephedra products with risk.

The first, as we've already heard, are some major manufacturers of ephedra products withheld information on reported adverse events while at the same time touting product safety. I as a physician had clinical research on less than 200 patients, yet I had documented the typical adverse event profile associated when ephedra ingested alone or in combination with caffeine. I surmised in the late 1990's that manufacturers must be withholding adverse events information as their reported absence of side effect was discordant with my own research data.

Radio ads and some product labels during this time period hailed the ephedra caffeine mixture as independently laboratory tested or clinical tested for safety. Some provided misleading scientific references in their product literature or websites.

Second, when those few investigators with experience in the areas spoke out, they were challenged by some manufacturers with lawsuits. When my colleague, Dr. George Blackburn at Harvard

publicly spoke of risks, he was unsuccessfully sued, but a bitter, painful and costly process nevertheless.

When I later publicly expressed my own safety concerns, attempts were made by a manufacturer to pressure me into silence from every direction; through the university, the hospital, by placing false but nevertheless damaging advertisements in major newspapers and by positioning me as having competitive industry ties.

Third, my professional view having carried out peer review research in the area for over 30 years, is that several of the widely cited ephedra studies are technically flawed and biased. They inappropriately highlight product effectiveness while at the same time minimize risks.

Through my experience with the ephedra products I have served as an expert witness in a number of lawsuits against manufacturers. This has provided me with the unique opportunity to review confidential documents, some of which are now publicly available, that reveal either serious errors or intentional fabrication that inappropriately provide an overly positive impression of some ephedra products.

Unsavory manufacturers learned quickly that a supportive published paper, whatever the quality, helps to gain credibility while neutralizing even the most ardent academic or governmental skeptic.

The ephedra products are banned in many parts of the world, and a similar trend is now taking place in some parts of the United States. Samuel Hopkins Adams was ultimately sued by manufacturers because of the articles he wrote, and I'll say unsuccessfully, following his milestone report. But this had little effect on the momentum shortly thereafter to create the FDA.

The time is right for you as legislators to again protect the American public by taking a strong and visionary position on dangerous dietary supplements for weight control.

Thank you.

[The prepared statement of Steven B. Heymsfield follows:]

PREPARED STATEMENT OF STEVEN B. HEYMSFIELD, PROFESSOR OF MEDICINE, COLUMBIA UNIVERSITY, COLLEGE OF PHYSICIANS AND SURGEONS, DEPUTY DIRECTOR, NEW YORK OBESITY RESEARCH CENTER, ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

WHAT IS A DIETARY SUPPLEMENT?

There exist three categories of chemical agents available for weight loss treatment. The first two categories are prescription drugs and over-the-counter drugs. The Federal Drug Administration (FDA) regulates these agents under carefully controlled guidelines for safety and efficacy. The process is particularly rigorous for weight loss agents as over 60% of Americans are now overweight or obese, excess adiposity effects increasing numbers of vulnerable children and adolescents, and drug treatments for weight loss have a notorious past history of both abuse and damaging physical and behavioral effects extending back over a century. Prescription and over-the-counter drugs are rigorously tested using modern scientific guidelines and procedures to ensure public and individual safety.

In 1994 a third category of agents emerged referred to as "dietary supplements". The term dietary supplements is a legal one as stated by the FDA:

"FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register with FDA nor get FDA

approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising."

Dietary supplements for weight loss, unlike traditional drugs, often include multiple ingredients; the word "supplement" is misleading as most agents do not "add" to the natural body stores of the compound nor does the agent usually prevent or correct a deficiency state.

WHAT ARE SOME OF THE MOST POPULAR WEIGHT LOSS PRODUCTS?

Weight loss can be produced when ingestion or absorption of calories or energy is less than energy released from the body as heat. Dietary supplements purportedly produce weight loss by suppressing appetite, reducing absorption, increasing heat production or metabolic rate, and changing the proportion of calories stored as fat and muscle.

The ephedra alkaloids, discussed below, are thought to suppress appetite and increase energy expenditure, by two different mechanisms. These actions are enhanced with herbal sources of caffeine and aspirin are added to the ephedra-containing product.

Some agents are reported to reduce fat and thus energy absorption from the gastrointestinal tract, notably chitosan. Chitin is a substance derived from the exoskeletons (shells) of arthropods such as crabs, shrimps, and lobster.

Some dietary supplements reportedly increase the storage of ingested nutrient as muscle and decrease the proportion stored as fat. These include the herbal ingredient *garcinia cambogia* and the widely used group of compounds referred to as chromium picolinate and other chromium salts.

My colleagues and I have reviewed these agents in a recent report (1).

I would now like to focus some specific comments on dietary supplements that include MaHuang as the main active ingredient. I select MaHuang because consumers are exposed with these products to a potentially dangerous family of ingredients, the ephedra alkaloids, that not only produce weight loss but that may lead to strokes and heart attacks with associated disability and death in selected susceptible patients.

A key concern is that overweight and obese patients are particularly vulnerable to taking purported dietary supplement weight loss products because they are often desperate, want to lose weight quickly, find physician evaluations time consuming and costly, and have often tried dietary and medical therapies of limited current effectiveness.

By avoiding medical oversight, overweight and obese consumers purchasing dietary supplements make the false assumption that dietary supplements and herbal preparations are inordinately safe and may pose no or very little risk. Moreover, many overweight and obese consumers harbor "silent" diseases such as high blood pressure and narrowing of the coronary arteries that manifest under the biological conditions produced with ingestion of the purported weight loss agent. The overweight consumer of dietary supplements who harbors a potentially silent killer may be bypassing the critical medical oversight needed to detect, prevent, or treat a serious underlying medical condition. A large percentage of overweight and obese Americans have undiagnosed and untreated medical conditions (2).

WHAT IS MAHUANG?

MaHuang, now defined as a dietary supplement in the US, is primarily used today as an ingredient in herbal weight loss products and acts to lower appetite and potentially increases energy expenditure through stimulant mechanisms (3-12).

MaHuang is the Chinese name of *Ephedra sinica*, an acrid tasting stimulant herb (1). Other *Ephedra* species include *Ephedra equisetina* and *Ephedra intermedia*.

WHAT ARE THE ACTIVE INGREDIENTS IN MAHUANG?

The ephedra alkaloids represent a family of compounds that vary in proportion depending on plant species, harvest season, weather conditions, geographic location, and other factors. The ephedra content of dietary may vary substantially from label claims (13).

The ephedra alkaloids include the major component, up to 90%, (-)-ephedrine, up to 30% pseudoephedrine, and lesser amounts of (+/-)-norephedrine or phenylpropanolamine, and (+)-norpseudoephedrine or cathine. The +/- refers to the three

dimensional positioning of atoms within the molecule and this feature of a molecule may influence its biological activity.

Ephedrine, an ephedra extract, was synthesized in 1927 and is also widely used today in weight loss and other pharmaceutical preparations, particularly in Europe. Although studies are limited, the pharmacokinetics of synthetic and botanical forms of ephedrine appear similar (14; Appendix I); some questions on drug disposition remain and more studies are needed (15). Pharmacokinetic properties of a drug describe its absorption, distribution, and elimination from the body.

The chemical structures of ephedrine and other ephedra alkaloids are very similar to the hormones epinephrine or adrenaline and nor-epinephrine. These are the “flight and fight” hormones that have many important biological effects including increasing blood pressure, respiration, heart rate, and arousal. Ephedra alkaloids are also very similar in structure to the banned group of chemical compounds referred to as amphetamines (Appendix II). Widely used five decades ago for weight loss and other stimulant effects, amphetamines are addicting and have many serious other side effects.

HOW DOES MAHUANG PRODUCE WEIGHT LOSS?

Ephedrine alkaloids appear to exert their main weight loss effects by suppressing appetite and thus food intake via central “sympathomimetic” (beta-agonist) actions. Ephedrine alkaloids also appear to have a small effect on increasing energy expenditure (16). Taken collectively, the ephedra family of compounds promotes negative energy balance and weight loss by lowering both energy intake and increasing energy expenditure. Ephedrine and other Ephedra alkaloids have variable stimulant effects (1,16).

Ephedrine and ephedra alkaloids alone have modest weight loss effects and their efficacy appears to be enhanced by addition of caffeine and aspirin either as the pharmaceutical grade ingredients or as their natural counterparts such as Guarana and Willow-bark, respectively (17-21).

Addition of caffeine (i.e., “Guarana”) and aspirin (i.e., Willow-bark) to MaHuang purportedly potentiates the actions of ephedrine. Caffeine competitively antagonizes adenosine receptors and may be an adrenaline antagonist; adenosine is a hormone produced by endothelial cells that dilates blood vessels. Many commercial weight loss preparations include varying proportions of these three components. Caffeine has a small thermogenic (i.e., heat-producing) effect in humans (16,17). Aspirin has actions that also potentiate ephedrine actions.

IS MAHUANG EFFECTIVE AS A WEIGHT LOSS AGENT?

There are many studies that have examined the effectiveness of ephedrine alone or in combination with other ingredients; fewer studies examine the weight loss effects of ephedra alkaloids in combination with other natural sources of caffeine and aspirin. The collective studies strongly support the premise that ephedrine, particularly in combination with caffeine and also aspirin, promote significant short-term (3-6 months) weight loss when ingested as part of an intervention program including dietary and lifestyle management. Long-term (>6 months) controlled trials with large and diverse subject populations are lacking. The evidence for ephedra efficacy is summarized in the recent Rand Report (Appendix III).

The efficacy of MaHuang, separate from that of chemically synthesized ephedrine, is supported by fewer published abstracts and papers, although conceptually, there is no reason to expect a “large” difference between “natural” ephedra and chemically-synthesized ephedrine. As noted earlier, the pharmacokinetics of chemically synthesized and botanical sources of ephedrine appear similar (Appendix I).

A major limitation of reviewed research is that most studies administered ephedrine or MaHuang in forms that mimic commercially available preparations and thus: the efficacy of ephedrine as a sole weight loss agent is not entirely clear and is questionable; the efficacy of ephedrine with varying amounts of caffeine and aspirin is difficult to ascertain as studies failed to include varying amounts of these other agents independent of ephedrine or as separate experimental limbs in controlled trials.

Ephedrine is used in association with caffeine and aspirin, or their herbal equivalents guarana and willow bark, to produce the “fat-burning stack (18).” The stack has some evidence to support its efficacy and is used in Europe. The three compounds, when taken in the following ratio, 200 mg caffeine/60mg ephedrine/300mg aspirin, produces a significant thermogenic effect. Very limited published information is available on the safety and efficacy of the “stack” or related products.

A concern is that the concentration of ephedrine in the plant and method of preparation vary widely among products (13). Product labels may therefore not reflect actual ingredient content or bioavailability.

ARE EPHEDRA-CONTAINING PRODUCTS SAFE?

Why do we know that ephedra alkaloids may be unsafe in some consumers? Scientists know that ephedra alkaloids, particular when used in combination with potentiating agents that include caffeine and aspirin, produce variable increases in blood pressure, heart rate, cardiac output, and respiration (Table 1). These effects in susceptible individuals can trigger heart attacks and strokes. These effects are well summarized in JAMA's patient page attached in Appendix IV.

The molecular basis of the stimulant effect for the class of compounds, "sympathomimetic agents", is well known. While the effects of ephedra alkaloids alone or in combination are often small in magnitude and transient, given the large and potentially medically vulnerable obese population taking these agents we can predict that some individuals will have a relatively large drug-induced biological effect. Others may have only a small effect, but remain medically vulnerable due to silent underlying heart or cerebrovascular diseases. Many of the patients taking these agents do so in the complete absence of medical supervision or evaluation. They may inadvertently take a large dose due to product variation or consciously in the hope of boosting their weight loss. Unsupervised, they may unduly exercise or take excessive amounts of caffeinated beverages or aspirin. The predictable result, given the millions of Americans taking these products, is serious medical events including heart attacks and strokes.

Given the well-recognized risks of this group of dietary supplements and the appropriate lack of interest in the area by pharmaceutical companies, there exist very few careful safety and efficacy trials that meet the current standards set forth for evaluation of pharmaceutical weight loss agents.

In the studies carried out by my colleagues and I using a commercial weight loss product containing ephedra and caffeine as active ingredients, some patients in the "active" treatment group experienced untoward effects at "usual" doses such as palpitations, blood pressure elevations, and other typical stimulant effects that led to their discontinuation in the study (21). I have observed similar effects in other unpublished ephedra studies carried out at our institution. These effects are the well characterized sympathomimetic effects that I mentioned earlier and that support our projection that some medically unscreened patients with underlying disease may suffer heart attacks and strokes following ingestion of this or similar dietary supplements. This projection is supported by the study of Haller and Benowitz (23)(Appendix V) and Bent et al (Appendix VI).

A concern regarding the well controlled clinical trials is that subjects were appropriately medically screened prior to entry into the trial so as to reduce the medical risks of those exposed. One such trial was carried out at our institution (22) and only those subjects deemed medically acceptable were entered into treatment. Rigorous testing of blood pressure and heart rhythm was used to detect and eliminate those subjects who may have suffered a serious adverse event during the trial. The lack of serious injuries and side effects in trials such as these cannot be interpreted as a safety endorsement as the actual consumer population still includes the medically vulnerable and unscreened individual who may harbor a potentially lethal silent disease manifest by ingestion of ephedra alkaloids.

Specifically, concerns have been raised about the safety of products containing MaHuang/ephedra. Several serious case-reports of adverse effects and fatalities have appeared in the literature. Strokes, myocardial infarction, and cardiac arrhythmias are reported in association with ephedra ingestion. Benowitz and Haller (23; Appendix VI) provided the FDA with an independent review of adverse events related to ephedra alkaloid containing supplements. The authors concluded that ephedra alkaloids may pose a health risk for selected individuals. Some of the reported side effects in patients occurred within the commonly used therapeutic ranges.

Ephedrine alone or combination with other ingredients may raise heart rate and blood pressure (e.g., systolic BP increase 3-7 mmHg) in some subjects (1-23), although the magnitude and length of time for which these adverse effects remain evident is not well established. Restlessness, headache, and insomnia have been reported by subjects ingesting some commercial dietary supplements and with synthetic ephedrine-caffeine combinations. Subjects with bleeding tendencies may be at risk when taking aspirin-like compounds.

MaHuang taken alone or combination with other agents may place certain subjects at risk of adverse and potentially fatal effects. More long-term safety data, beyond six months, is needed, particularly in selected populations such as the elderly.

Finally, there exists particularly vulnerable populations such as pregnant or lactating women, the elderly, and subjects with eating disorders in whom particular concern exists for their use of weight loss dietary supplements.

SHOULD THE REGULATIONS FOR DIETARY SUPPLEMENTS BE CHANGED?

Although my review here has been brief and focused, we can envision four groups of dietary supplement for weight loss: safe and ineffective; effective but unsafe; ineffective and unsafe; effective and safe. At present most of the available dietary supplements fall into one of the first two categories.

Safe and ineffective: This group of products provides false hope to the unwitting highly vulnerable overweight or obese consumer and may delay their entry into an appropriate medical or nutritional care system.

Effective but unsafe: This group of products is more dangerous and actual product efficacy will lure consumers into trying the product while erroneously assuming dietary supplements, because of their herbal or natural ingredients are unduly safe compared to their pharmaceutical counterparts. As stated in the JAMA patient page (Appendix IV), the risks of ephedra far outweigh benefits.

Improved product safety testing, quality control, labeling, and nomenclature are all needed in order to forestall or eliminate the problems now inherent with the dietary supplement category of weight loss products.

Table 1. Patterns of Signs and Symptoms Associated With Dietary Supplements Containing Ephedrine Alkaloids ¹

Organ/system involved	Clinical significance	Signs and symptoms
Cardiovascular system.	Serious Less clinically significant	Dysrhythmias, severe hypertension, cardiac arrest, angina, myocardial infarction, and stroke ² Tachycardia, mild hypertension, palpitations.
Nervous system	Serious Less clinically significant	Psychosis, suicidal, altered or loss of consciousness (including disorientation or confusion), and seizures. Anxiety, nervousness, tremor, hyperactivity, insomnia, altered behavior, memory changes.
Gastrointestinal (GI).	Serious Less clinically significant	Altered serum enzymes, hepatitis. GI distress (nausea, vomiting, diarrhea, constipation).
Dermatologic	Serious Less clinically significant	Exfoliative dermatitis Less clinically significant Nonspecific rashes.
General manifestations.		Numbness, tingling, dizziness, fatigue, lethargy, weakness.

¹ Reproduced from Federal Register: June 4, 1997 (Volume 62, Number 107), Dietary Supplements Containing Ephedrine Alkaloids.

² For the purposes of this document, strokes (i.e., cerebrovascular accidents) are considered to be related to the cardiovascular system, because predisposing or inciting factors include hypertension, dysrhythmias and ischemia, although it is recognized that the consequences affect the central nervous system.

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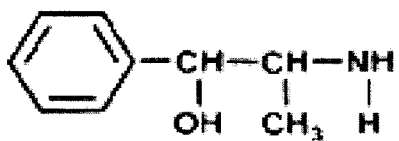
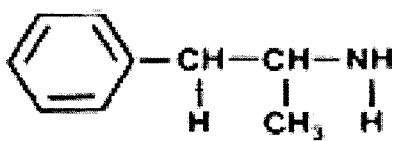
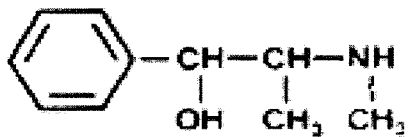
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Benowitz NL, Haller CA. Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids. *New Engl J Med*

Appendix I**Pharmacology of ephedra alkaloids and caffeine after single-dose dietary supplement use.****Haller CA, Jacob P 3rd, Benowitz NL.**

Division of Clinical Pharmacology, San Francisco General Hospital, University of California, 94143, USA. dchaller@worldnet.att.net

OBJECTIVE: Serious cardiovascular toxicity has been reported in people taking dietary supplements that contain ma huang (Ephedra) and guarana (caffeine). We assessed the pharmacokinetics and pharmacodynamics of a dietary supplement that contains these herbal stimulants. **METHODS:** Eight healthy adults received a single oral dose of a thermogenic dietary supplement labeled to contain 20 mg ephedrine alkaloids and 200 mg caffeine after an overnight fast. Serial plasma and urine samples were analyzed by use of liquid chromatography-tandem mass spectrometry for ephedrine alkaloid and caffeine concentrations, and heart rate and blood pressure were monitored for 14 hours. **RESULTS:** Plasma clearance and elimination half-lives for ephedrine, pseudoephedrine, and caffeine were comparable to published values reported for drug formulations. A prolonged half-life of ephedrine and pseudoephedrine was observed in 1 subject with the highest urine pH. Mean systolic blood pressure increased significantly to a maximum of 14 mm Hg above baseline at 90 minutes after ingestion ($P < .001$). There was a lag in the mean heart rate response that reached a maximum change of 15 beats/min above baseline at 6 hours after ingestion ($P < .001$). Diastolic blood pressure changes were insignificant. Two subjects who were taking oral contraceptives had longer caffeine half-lives (15.5 \pm 0.3 hours versus 5.6 \pm 1.7 hours) and lower values for oral clearance (0.34 \pm 0.01 mL/min. kg versus 0.99 \pm 0.41 mL/min. kg) than subjects who were not taking oral contraceptives. **CONCLUSIONS:** Botanical stimulants have disposition characteristics similar to their pharmaceutical counterparts, and they can produce significant cardiovascular responses after a single dose.

Appendix II**PHENYLPROPANOLAMINE****AMPHETAMINE****EPHEDRINE**

REVIEW

Appendix III

Efficacy and Safety of Ephedra and Ephedrine for Weight Loss and Athletic Performance

A Meta-analysis

Paul G. Shekelle, MD, PhD

Mary L. Hardy, MD

Sally C. Morton, PhD

Margaret Magione, MPP

Walter A. Mojica, MD, MPH

Marika J. Sutorp, MS

Shannon L. Rhodes, MFA

Lara Jungvig, BA

James Gagne, MD

USE OF EPHEDRINE ALKALOID-containing products to promote weight loss or to enhance athletic performance has garnered a great deal of recent attention, due in part to a number of well-publicized adverse events reportedly associated with the use of ephedra- or ephedrine alkaloid-containing products.^{1,2} These reports have led several groups to ask the US Food and Drug Administration (FDA) to ban the production and sale of ephedra products.³ Advocates counter that ephedra is safe and effective.⁴ The US Department of Health and Human Services requested this synthesis of available evidence regarding efficacy and safety of ephedra use to clarify the existing state of the science on ephedrine alkaloids. The National Institutes of Health will use this information to guide an expanded research effort to better understand the safety of ephedrine alkaloids.⁶

See also p 1568 and Patient Page.

Context. Ephedra and ephedrine sometimes are used for weight loss or enhanced athletic performance, but the efficacy and safety of these compounds are uncertain.

Objective. To assess the efficacy and safety of ephedra and ephedrine used for weight loss and enhanced athletic performance.

Data Sources. We searched 9 databases using the terms *ephedra*, *ephedrine*, *adverse effect*, *side effect*, *efficacy*, *effective*, and *toxic*. We included unpublished trials and non-English-language documents. Adverse events reported to the US Food and Drug Administration MedWatch program were assessed.

Study Selection. Eligible studies were controlled trials of ephedra or ephedrine used for weight loss or athletic performance and case reports of adverse events associated with such use. Eligible studies for weight loss were human studies with at least 8 weeks of follow-up, and for athletic performance, those having no minimum follow-up. Eligible case reports documented that ephedra or ephedrine was consumed within 24 hours prior to an adverse event or that ephedrine or an associated product was found in blood or urine, and that other potential causes had been excluded. Of the 530 articles screened, 52 controlled trials and 65 case reports were included in the adverse events analysis. Of more than 18 000 other case reports screened, 284 underwent detailed review.

Data Extraction. Two reviewers independently identified trials of efficacy and safety of ephedra and ephedrine on weight loss or athletic performance; disagreements were resolved by consensus. Case reports were reviewed with explicit and implicit methods.

Data Synthesis. No weight loss trials assessed duration of treatment greater than 6 months. Pooled results for trials comparing placebo with ephedrine ($n=5$), ephedrine and caffeine ($n=12$), ephedra ($n=1$), and ephedra and herbs containing caffeine ($n=4$) yielded estimates of weight loss (more than placebo) of 0.6 (95% confidence interval, 0.2-1.0), 1.0 (0.7-1.3), 0.8 (0.4-1.2), and 1.0 (0.6-1.3) kg/mo, respectively. Sensitivity analyses did not substantially alter the latter 3 results. No trials of ephedra and athletic performance were found; 7 trials of ephedrine were too heterogeneous to synthesize. Safety data from 50 trials yielded estimates of 2.2- to 3.6-fold increases in odds of psychiatric, autonomic, or gastrointestinal symptoms, and heart palpitations. Data are insufficient to draw conclusions about adverse events occurring at a rate less than 1.0 per thousand. The majority of case reports are insufficiently documented to allow meaningful assessment.

Conclusions. Ephedrine and ephedra promote modest short-term weight loss (~ 0.9 kg/mo more than placebo) in clinical trials. There are no data regarding long-term weight loss, and evidence to support use of ephedra for athletic performance is insufficient. Use of ephedra or ephedrine and caffeine is associated with increased risk of psychiatric, autonomic, or gastrointestinal symptoms, and heart palpitations.

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Author Affiliations are listed at the end of this article.
Corresponding Author and Reprints: Paul G. Shekelle, MD, PhD, Southern California Evidence-based

Practice Center-RAND, 1700 Main St, PO Box 2138, Santa Monica, CA 90407-2138 (e-mail: shekelle@rand.org).

Appendix IV

Ephedra and Ephedrine

Ephedra is a plant-based substance from the herb *Ephedra sinica*. Ephedra is used in many over-the-counter weight loss products. It is also used by some athletes who believe it can improve their performance. It may be combined with herbs containing caffeine (such as *guarana*) or with other substances in these supplements. Ephedra, also known as *ma huang*, has also been used in traditional Chinese medicine to treat asthma or other lung problems. Because ephedra is marketed by companies as a **supplement** (not a drug to treat a disease), the US Food and Drug Administration (FDA) does not regulate its use. However, many serious **adverse** (bad) effects related to ephedra use have been reported. Recent research has shown that use of ephedra appears to be more risky than use of other herbal preparations.

The March 26, 2003, issue of JAMA includes an article about the efficacy and safety of ephedra and ephedrine.

EPHEDRINE

Ephedrine is a chemical contained in the ephedra herb. Ephedrine has medical uses, mostly in operating rooms and intensive care units. Its chemical properties raise blood pressure and heart rate and open up the large air passages in the lungs. Ephedrine is safe when used under the supervision of a doctor and with proper monitoring of the patient. Ephedrine has also been used as a weight loss product and by athletes who believe it makes them stronger or have more energy and endurance. However, this has not been proven and this type of unmonitored use for nonmedical reasons may not be safe.

POSSIBLE ADVERSE EFFECTS OF EPHEDRA AND EPHEDRINE

- Elevated blood pressure
- Nausea
- Heart attack
- Palpitations
- Agitation or restlessness
- Stroke
- Headache
- Psychiatric disturbances
- Death

Individuals with very high risks for adverse effects include children younger than 18 years; women who are pregnant or nursing; individuals who have health conditions such as high blood pressure, heart disease, seizure disorder, depression, diabetes, thyroid or liver disorders; and those who are using prescription medicines.

For anyone, the risks of bad effects from ephedra or ephedrine products far outweigh the possible minimal benefits. Products that are natural or plant-based are not necessarily safe just because they come from plants. Plants produce chemicals that can be dangerous and may interact with other medications you are taking. Discuss with your doctor any herbal or plant-based products you use.

REPORTING ADVERSE EVENTS

If you believe you have experienced a harmful side effect from ephedra or ephedrine, you or your doctor should report it to the FDA. The FDA has a hotline called **MEDWATCH** (800/FDA-1088) for reporting problems connected with the use of supplements, drugs, or medical devices. Your identity will be kept confidential. You may also use the FDA Web site (see For More Information) to access **MEDWATCH** for online reporting.

FOR MORE INFORMATION

- US Food and Drug Administration (includes a link to **MEDWATCH** to report adverse events)
www.fda.gov
- National Center for Complementary and Alternative Medicine
www.nccam.nih.gov
- National Institutes of Health Office of Dietary Supplements
dietary-supplements.info.nih.gov

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Joan M. Tarry, MD, Writer
Cassio Lynn, MA, Illustrator
Richard M. Glass, MD, Editor

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Appendix V

Adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids.

Haller CA, Benowitz NL.

Department of Medicine, University of California, San Francisco, and the California Poison Control System, 94143-1220, USA.

BACKGROUND: Dietary supplements that contain ephedra alkaloids (sometimes called ma huang) are widely promoted and used in the United States as a means of losing weight and increasing energy. In the light of recently reported adverse events related to use of these products, the Food and Drug Administration (FDA) has proposed limits on the dose and duration of use of such supplements. The FDA requested an independent review of reports of adverse events related to the use of supplements that contained ephedra alkaloids to assess causation and to estimate the level of risk the use of these supplements poses to consumers. **METHODS:** We reviewed 140 reports of adverse events related to the use of dietary supplements containing ephedra alkaloids that were submitted to the FDA between June 1, 1997, and March 31, 1999. A standardized rating system for assessing causation was applied to each adverse event. **RESULTS:** Thirty-one percent of cases were considered to be definitely or probably related to the use of supplements containing ephedra alkaloids, and 31 percent were deemed to be possibly related. Among the adverse events that were deemed definitely, probably, or possibly related to the use of supplements containing ephedra alkaloids, 47 percent involved cardiovascular symptoms and 18 percent involved the central nervous system. Hypertension was the single most frequent adverse effect (17 reports), followed by palpitations, tachycardia, or both (13); stroke (10); and seizures (7). Ten events resulted in death, and 13 events produced permanent disability, representing 26 percent of the definite, probable, and possible cases. **CONCLUSIONS:** The use of dietary supplements that contain ephedra alkaloids may pose a health risk to some persons. These findings indicate the need for a better understanding of individual susceptibility to the adverse effects of such dietary supplements.

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BRIEF COMMUNICATION

The Relative Safety of Ephedra Compared with Other Herbal Products

• Stephen Bent, MD; Thomas N. Tiedt, PhD; Michelle C. Odden, BS, and Michael G. Shipok, MD, MPH

Background: Ephedra is widely used in dietary supplements that are marketed to promote weight loss or increase energy; however, the safety of this product has been questioned because of numerous case reports of adverse events.

Objective: To compare the risk for adverse events attributable to ephedra and other herbal products.

Design: Comparative case series.

Setting: American Association of Poison Control Centers Toxic Event Surveillance System Database Annual Report, 2001.

Measurements: The relative risk and 95% confidence interval for experiencing an adverse reaction after ephedra use compared with other herbs. This risk was defined as the ratio of adverse reactions to ephedra versus other products, divided by the ratio of their relative use in the United States.

Results: Products containing ephedra accounted for 64% of all adverse reactions to herbs in the United States, yet these products represented only 0.62% of herbal product sales. The relative risks for an adverse reaction in persons using ephedra compared with other herbs were extremely high, ranging from 100 (95% CI, 83 to 140) for kava to 720 (CI, 520 to 1100) for *Ginkgo biloba*.

Conclusions: Ephedra use is associated with a greatly increased risk for adverse reactions compared with other herbs, and its use should be restricted.

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For author affiliations, see end of text.

An Asian ephedra species has been used for thousands of years in Traditional Chinese Medicine herbal formulas designed to treat asthma and other respiratory diseases (1, 2). The herb extract is known as ma huang and contains several ephedra alkaloids, including the primary active constituent, ephedrine, as well as smaller amounts of pseudoephedrine, phenylpropanolamine, methylephedrine, methypseudoephedrine, and norepseudoephedrine (ephedrine, a controlled substance) (3). These drugs have sympathomimetic activity and lead to various physiologic responses, including vasoconstriction, bronchodilation, and increases in blood pressure, heart rate, cardiac contractile force, and automaticity (4). Ephedra gained widespread medical use in the United States in the 1920s as a nasal decongestant, central nervous system stimulant, and asthma treatment, but use declined substantially in the following decade because of safety concerns and the availability of safer alternatives (5, 6).

Mr. GREENWOOD. Thank you very much, Dr. Heymsfield.
Dr. Woosley.

TESTIMONY OF RAYMOND WOOSLEY

Mr. WOOSLEY. Mr. Chairman Greenwood, members of the Committee and Congresswoman Davis.

Thank you for the opportunity to testify before this Committee on this very important topic.

Since 1995 I have served as a consultant to the Center for Food Safety and Nutrition of the FDA addressing their concern over the large number of reports of serious adverse reactions to ephedra-containing dietary supplement. I am very proud in 2001, I was awarded the FDA Commissioners' special citation for my work on ephedra for the FDA.

I have no financial interest in this question, and I do not represent any particular organization. But, since 1995, I and many other consultants to the FDA have recommended that the FDA take steps to have nonprescription products containing ephedrine removed from the market. I based this recommendation on my experience as a scientist and as a physician studying the actions of drugs in humans.

My credentials are summarized in my written testimony. I have been a professor of pharmacology and medicine at Vanderbilt University, Georgetown University and I am now Vice President for Health Sciences at the University of Arizona. For 39 years I have studied the actions of drugs in humans.

In 1995 and again in the year 2000 I was asked by the FDA to perform an in depth review of over 230 reports of adverse events related to the use of dietary supplements containing ephedra alkaloids. Each time I recommended these products be removed from the market because of a danger to the public. In congressional hearings I have made that recommendation.

Many agencies and regulatory bodies, such as Health Canada, the Canadian equivalent to our FDA, have already taken action to protect the public from these products.

We have heard that Illinois has banned the sale of these products and New York and California are considering legislation to take such action.

The U.S military and the National Football League prohibit the use of ephedra-containing products.

The American Medical Association, the American Heart Association, the American Society for Clinical Pharmacology and Therapeutics and many other professional organizations have called for FDA action to remove these products from the market.

What does it take? Dozens of deaths reported to the FDA and an unknown number of unreported deaths are reason enough for the FDA to take action. They are authorized.

The FDA has failed to act and only called for further study. They contracted with the Rand Corporation to perform an analysis of the published studies of these products. People died while this document was being created, needlessly. And, unfortunately, this analysis is not even relevant to the way ephedra is used in this nation today.

Because these products are taken as nonprescription dietary supplements and they are used without any medical supervision or medical screening, yet the scientific papers reviewed by Rand, every subject was screened by a physician or by a medical practitioner. If they had pre-existing medical conditions, they couldn't be enrolled. People enrolled in these trials were followed with close supervision. That isn't the way ephedra is used by the public today. So the analysis by Rand is really irrelevant. It is interesting, it is consistent, but it is irrelevant.

As an example, in the study by Boozer et.al., it is often cited as evidence for the safety of these products, the investigators excluded one of every 10 subjects that they interviewed because they had medical conditions that made ephedra and the caffeine product combination that they were studying, in their estimation unsafe. Studies with that medical screening are not feasible or even ethical, because the general knowledge in the medical community, the medical community knows that ephedra-containing products are dangerous. Any institutional review board responsible for the protection of human subjects will not approve a research protocol unless it includes medical screening and monitoring for safety. So this cannot be further studied. We do not need further study.

It, therefore, is not surprising that the published reports using medical screening failed to detect the kind of toxicity that we have heard about today and the FDA has looked at for over 8 years. The available evidence clearly shows that these products cause harm to some individuals, harm that cannot be prevented by warning labels. Because most patients do not know that they are at risk. Based on the Boozer trial, approximately 10 percent of patients who would like to take a dietary supplement for weight loss do not know that they have a medical condition until they are screened.

In summary, I strongly encourage you to ask the FDA to take action to ban the marketing of dietary supplements that contain ephedra. I also ask you to consider enacting legislation that will more accurately distinguish between drugs such as ephedra and dietary supplements. That will assist the FDA in regulating these products.

Ephedra containing products, and many others, are not dietary supplements. That is, they are not a necessary ingredient in a healthy diet. They are drugs and they should be regulated as drugs. Please do not call for warnings. Please do not call for more studies. People will die while those studies and those warnings are ineffective.

[The prepared statement of Raymond Woosley follows:]

PREPARED STATEMENT OF RAYMOND L. WOOSLEY, VICE PRESIDENT FOR HEALTH SCIENCES, UNIVERSITY OF ARIZONA

Mr. Chairman and members of the Committee: Thank you for the opportunity to testify before the Committee on the very important topic, i.e. the dangers of dietary supplements that contain ingredients from the plant ephedra or the chemical ephedrine. Since 1995, I have served as a consultant to the Center for Food Safety and Nutrition of the Food and Drug Administration to address their concern over the large number of severe adverse reactions with ephedrine-containing dietary supplements reported to the FDA. In 2001, I was awarded the FDA Commissioner's Special Citation for my work on ephedrine for the FDA. I have no financial interests in this question and I do not represent any particular organization.

I have consistently recommended that the FDA take steps to have non-prescription products containing ephedrine removed from the market. In 2001, I joined Public Citizen, a consumer advocacy organization, and filed a citizen's petition calling for an FDA ban on ephedrine-containing dietary supplements. I base this recommendation on my almost forty years of experience as a scientist and physician studying the actions of drugs in humans. In 1967, I obtained a PhD in pharmacology, i.e., the study of the actions of drugs. I obtained an MD from the University of Miami and then trained in Internal Medicine at Vanderbilt University. I then completed a fellowship in the subspecialty of clinical pharmacology, i.e. the study of the actions of drugs in humans. I rose to the rank of Professor of Medicine and Pharmacology at Vanderbilt University before moving to Georgetown University School of Medicine to Chair the Department of Pharmacology. I am now Vice President for Health Sciences at the University of Arizona and Director of one of the seven Centers for Education and Research on Therapeutics funded by the Agency for Healthcare Research and Quality. For the last 39 years I have studied the actions of drugs. I have been asked to serve as an advisor to the NIH, the FDA, the DOD and all of the leading pharmaceutical companies on the actions of drugs in humans. My experience has given me a broad perspective and an expertise in the toxicity of drugs. I served as co-director of the NIH-sponsored Cardiac Arrhythmia Suppression Trial that found certain drugs designed to save lives were actually causing tens of thousands of deaths each year. I also served as leader of the team that determined the mechanism of cardiac toxicity caused by terfenadine (Seldane[®]) which served as the basis for its ultimate removal from the market. I currently lead a team of scientists who are studying 50 prescription drugs that have the potential to induce life-threatening arrhythmias.

In 1995 and again in 2000, I was asked by the FDA to review over 230 reports of adverse events related to the use of dietary supplements containing ephedra alkaloids. The following is the conclusion of my most recent report: *"The occurrence of serious side effects makes the use of ephedrine containing products as dietary supplements at dosages that can increase blood pressure and heart rate in susceptible individuals unacceptable without medical supervision."*

Many agencies and regulatory bodies such as Health Canada have already taken action to protect the public from ephedrine-containing products. Two states have banned the sale of these products and the California legislature is now considering such action. The US Military and the National Football League prohibit the use of ephedrine-containing products. The American Medical Association, the American Heart Association, the American Society for Clinical Pharmacology and Therapeutics, and many other professional organizations have called for FDA action to remove these products from the market. Dozens of deaths reported to the FDA and an unknown number of unreported deaths are reason enough for the FDA to take action. However, a year ago, the FDA refused to act on our petition and called for further study. They contracted with the RAND Corporation to perform an analysis of the published studies and FDA reports of adverse events that might pertain to the safety and effectiveness of dietary supplements containing ephedrine or ephedrine with caffeine taken for weight loss or exercise enhancement.

However, such an analysis is not relevant to the way ephedrine is used by the public. Since these products are taken as non-prescription "dietary supplements", they are used without any medical screening or medical supervision. However, the scientific papers that were analyzed by RAND were studies in which subjects had been screened for pre-existing medical conditions and were followed during the trials under medical supervision. As an example, in the study by Boozer *et al.* (Int. J. Obes. Relat. Metab. Disord. 26(5):593-604, 2002) that is often cited as evidence for the safety of these products, the investigators excluded one of every ten subjects they screened because they found medical conditions that made ephedra/caffeine, in their estimation, unsafe. RAND could not find published trials that truly addressed the question posed by FDA. Such studies *without* medical screening are not feasible or ethical because of the general knowledge in the medical community that ephedrine-containing products are dangerous. Any Institutional Review Board responsible for the protection of human subjects would not approve a research protocol unless it included medical screening and monitoring for safety. It is therefore not surprising that the published reports that include only small numbers of subjects who had been medically screened failed to detect the type of toxicity reported to the FDA.

The ephedrine industry has raised doubts about the validity of the adverse events reported to the FDA. Determination of causation for rare adverse events can be difficult when analyzing a single report. However, one must consider the totality of evidence for scientific validity and consistency with the drugs pharmacologic actions. After considering the information in the adverse events reported and the totality of

information about ephedrine, I concluded that the use of these products causes a serious health risk to the public. Decades of experience summarized in textbooks of medicine and pharmacology support this conclusion. The RAND analysis of these reports failed to adequately consider the pharmacology and clinical pharmacology of adrenaline-like chemicals such as ephedrine. Also, the consistency of the evidence across a range of chemically-related substances must be considered. The relative safety and efficacy of other drugs that have similar pharmacologic actions is especially relevant. Every drug with adrenalin-like actions that increases blood pressure and heart rate, i.e. they mimic the human body's emergency "autonomic" nervous system, has been already associated with serious cardiovascular and neurologic adverse events. Likewise, the actions of drugs that antagonize the effects of ephedrine should be considered. For example, drugs that block the actions of adrenaline reduce the incidence of strokes and heart attacks. The ephedrine data are consistent with the observation of a high risk of stroke with the diet pills containing phenylpropanolamine (PPA), a drug with almost the same chemical structure as ephedrine. In this case, the FDA took action to remove products with PPA from the market.

Another related weakness of the RAND assessment is the absence of consideration of the genetic diversity that we know exists in large populations of people. Most of the studies reviewed enrolled only 50-200 patients and all had been medically screened. It is very unlikely that these studies would include any of the 1 in 10,000 patients at risk for super-sensitivity to ephedrine due to a genetic variant that would be otherwise silent.

The available evidence clearly shows that these products cause harm in some individuals that cannot be prevented by warning labels because most patients will not know they are at risk of experiencing adverse effects. Based upon the Boozer trial, approximately 10% of patients will have medical conditions that place them at increased risk of adverse effects. I hope you will take swift action to protect these people.

RECOMMENDATIONS

In summary, I strongly encourage you to ask the FDA to ban these products. I have no doubt that these products are causing needless death and disability to people.

I also ask you to consider enacting legislation that will more accurately distinguish between "drugs" and "dietary supplements" and clarify how the FDA should regulate these products. Many of the products that are marketed as dietary supplements and especially the ephedrine-containing products are in fact drugs because they are not normal constituents of a healthy diet. The ephedrine products are being used by and being promoted to the public for weight loss. Without medical supervision these products present a clear and serious danger to the public and should be regulated as medicines and banned for use without a prescription.

Thank you for the opportunity to provide this statement for the record.

Mr. GREENWOOD. I thank you very much, Dr. Woosley.
Dr. Zipes.

TESTIMONY OF DOUGLAS P. ZIPES

Mr. ZIPES. Mr. Chairman, members of the committee, Ms. Davis, I am a clinical cardiologist and my area of expertise is in heart rhythm problems.

I would like to start with a potential conflict of interest. I am an expert witness for Plaintiff for McDonald's v. Twin Labs, which is an ephedra case, but I am also expert for Defense of four pharmaceutical companies with drugs unrelated to ephedra.

Ephedra and ephedrine actions on the heart and blood vessels are to produce an adrenaline like effect. This is a stimulant, a "fight" or "flight" type reaction. It is also a brain stimulant and it is related to methamphetamine or speed.

Caffeine also has actions on the heart and blood vessels and is also a stimulate, and therefore adds to the effects of ephedra actions. And, indeed, an exercising individual super imposes even additional adrenaline effect on the actions of these two drugs.

So in general what happens? The blood pressure elevates, the heart rate elevates, there's elevated stress on the heart. These changes can reduce a very critical electrolyte, potassium in the blood and all these changes then can cause heart rhythm disorders ranging from palpitations due to premature beats or ventricular fibrillation. This is the abnormal heart rhythm coming from the bottom chamber of the heart at rates of 4 to 600 times a minute that produce sudden death.

Now what evidence exists that ephedra compounds can produce these effects? Certainly animal and clinical studies establish the adrenaline like effects. That is not in argument. The question is, though, what are the adverse effects? And they come from adverse event reports, case reports and some controlled trials.

Now, in general adverse event reports and case reports provide less robust data than controlled clinical trials. But they may be the only source of information about infrequently occurring side effects, those that occur in less than 1 in a 1,000 or so individuals. However, we can establish criteria that allow us to investigate those adverse event reports. And I have six here which I use when I evaluate a drug.

Is there a temporal relationship between ingestion and adverse event?

Is an appropriate dose taken to have an adverse effect?

Are all other causes for the adverse event recognized and ruled out?

Is there biological plausibility? By that I mean, the known influence of the adrenaline stimulation of these drugs can cause these events. We know that from animal and clinical investigation. Is there a D or rechallenge? In other words, when the drug is stopped, do the adverse events stop or if the drug is taken again, is there another adverse events and are there supported published literature?

And I would suggest that many of the published reports on ephedra and ephedrine compounds include individuals who unquestionably meet these criteria.

So I think to a reasonable degree of medical and scientific certainty, it is my opinion that ephedra, ephedrine compounds can cause the following adverse events:

There are minor adverse events such as nausea, dry mouth, shakiness and insomnia, but critically the major events on the heart are palpitations but ventricular fibrillation and sudden death.

My recommendations to the committee are that they recognize that ephedra and ephedrine are drugs, they are not dietary supplements. Recognize that they are capable of provoking harm including ventricular fibrillation and sudden death. Element over-the-counter use based on minor proven benefits and potential for major harm, and regulate its use by applying FDA criteria to ephedra and ephedrine compounds as is applied for all other drugs.

Thank you for your attention.

[The prepared statement of Douglas Zipes follows:]

PREPARED STATEMENT OF DOUGLAS P. ZIPES, DISTINGUISHED PROFESSOR OF MEDICINE, PHARMACOLOGY AND TOXICOLOGY, EMERITUS, DIRECTOR OF THE KRANNERT INSTITUTE OF CARDIOLOGY AND DIVISION OF CARDIOLOGY, INDIANA UNIVERSITY SCHOOL OF MEDICINE

I. INTRODUCTION

I am a clinical cardiologist and scientist specializing in heart rhythm disturbances. The findings and opinions that follow are based upon my education, training and experience in medicine, cardiology, cardiovascular pharmacology, cardiac electrophysiology, and review of the medical literature.

Recent articles in the medical literature highlight the concern of medical practitioners with the overall quality, safety, and efficacy of some herbal products.¹ In my opinion, the Dietary Supplement Health and Education Act (DSHEA) passed in 1994 has not provided a satisfactory framework to protect the public health by allowing dietary supplements to be marketed without prior approval of efficacy or safety by the FDA. Though DSHEA limits certain health claims for dietary supplements, these products are marketed in such a way that consumers believe they are effective to cure or treat many of the conditions that afflict the population, including obesity. Laboratory analysis of these products² has disclosed that there is considerable variation in the composition of herbal supplements from one manufacturer to another and often from lot to lot from the same manufacturer. Most of these herbal products have not been tested rigorously, with the accepted norm of standardized, controlled, prospective, randomized trials that we use to test medical drugs and devices. In addition to lack of efficacy for the claimed use, some of these products produce important side effects either directly or by interactions between the herbal remedies and prescription drugs and over-the-counter (OTC) drugs. Due to limitations in the reporting system, it is estimated that less than one percent (1%) of the adverse effects caused by dietary supplements are reported to the FDA.³ The current regulatory framework requires that, if a safety concern arises, the burden of proof for safety lies not with the manufacturer but with the FDA to prove that the product is unsafe. In particular, dietary supplements containing ephedra and caffeine illustrate the health risks posed to consumers from the current system and will be the focus of this report.

II. NORMAL HEART FUNCTION

The heart and blood vessels provide oxygen and nourishment to every cell of the body and remove waste material by circulating blood throughout the body. The heart contracts, pumping about 5 quarts (4.7 liters) of blood every minute, or 1800 gallons (6768 liters) of blood every day. Oxygenated blood is pumped from the left ventricle to the body to provide oxygen and nutrients, while returning (deoxygenated) blood is pumped through the lungs from the right ventricle to remove carbon dioxide and become re-oxygenated. This continuous cycle of synchronized contractions is driven by the heart's electrical system.

A healthy heart beats steadily and rhythmically at a rate of about 60 to 100 beats per minute when at rest (normal sinus rhythm). During strenuous exercise, the heart can increase the amount of blood it pumps fourfold. The normal heart beats approximately 38 million times per year, or about 3 billion times in a normal lifespan. The sinus node, a small group of specialized cells in the top right portion of the heart's upper chamber (atrium), serves as the pacemaker, initiating and orchestrating each heartbeat. Other tissues in the heart wait for the arrival of each sinus-generated beat, almost like electricity traveling over a wire, and fire in an orderly sequence, from the atria to the ventricles, to produce each heartbeat.

Multiple factors can influence the rate of discharge of the sinus node and can cause other tissues in the heart to fire prematurely and usurp control of the heartbeat. Among these factors, the *autonomic nervous system* is most prominent.⁴ Predominantly two groups of nerves make up the autonomic nervous system: *vagus nerves* and *sympathetic nerves*. The vagus nerves exert an inhibitory effect on heart function by release of a substance called *acetylcholine*, slowing the heart rate, slowing conduction from the atria to bottom chambers (ventricles), lessening the strength of heart muscle contraction and dilating blood vessels. They oppose the action of sympathetic nerves. Sympathetic nerves are stimulatory by release of substances known collectively as *catecholamines* (adrenaline or epinephrine, and noradrenaline or norepinephrine), causing an increase in the heart rate, a quickening of conduction between the atria and ventricles, an increase in the strength of heart muscle contraction, and, for the most part, a constriction of the blood vessels. These actions result in an increase in blood pressure and also can provoke spontaneous discharge of the heartbeat from areas other than the sinus node. When

heart tissue other than the sinus node initiates a heartbeat, this results in arrhythmias, or disorders of the heartbeat. The extent of the heartbeat disorder can range from a single premature beat, often felt as a “thump” in the chest or palpitation, to a lethal heart rhythm called ventricular fibrillation. The latter arrhythmia is the major cause of sudden cardiac death. It is a disorganized, rapid (400-600 times per minute) heart rhythm originating in the bottom chambers (ventricles) and preventing blood flow to the brain, which causes death in 3-5 minutes unless reversed.^{5,6}

III. ACTION OF EPHEDRA AND CAFFEINE ON THE HEART AND BLOOD VESSELS

A. Ephedra/ephedrine

The ephedra products under discussion are marketed as dietary supplements for weight loss and to boost energy. These preparations stimulate both the heart and blood vessels, and the brain. They are chemically related to methamphetamine.⁷ Most of these ephedra substances contain extracts of the ma huang plant, which is referred to as ephedra. Ephedra contains primarily ephedrine, which is a sympathomimetic amine. That means its actions mimic those actions produced by stimulation of the sympathetic nerves, noted above. Ephedra does this by both a direct effect on stimulating alpha and beta 1 and beta 2-adrenergic receptors, as the body's own catecholamines do, and indirectly by stimulating the release of the body's store of catecholamines and another compound called dopamine (20-30% increase). Ephedra can be chemically synthesized as ephedrine, rather than extracted from a plant, and has the same actions.

B. Caffeine

Most of these ephedra products also contain caffeine, typically extracts from guarana seed. Caffeine causes an anti-vagal effect by antagonizing the actions of adenosine, and can therefore promote vasoconstriction (blood pressure elevation) and increase the release of epinephrine, norepinephrine and dopamine.

Importantly, an exercising individual normally activates the autonomic nervous system to decrease vagal, and increase sympathetic, activity. These changes summate with the actions of ephedra and caffeine.

C. Physiologic effects

The result of the actions of ephedra and caffeine noted above is to:

- 1) Elevate the blood pressure
- 2) Elevate the heart rate
- 3) Put more stress on the heart (needs more oxygen)
- 4) Reduce the potassium level in the blood

These responses to ephedra/caffeine compounds can cause abnormal heart rhythms ranging from single premature beats to ventricular fibrillation and sudden death

IV. WHAT EVIDENCE EXISTS TO SHOW THAT EPHEDRA COMPOUNDS CAN CAUSE CARDIOVASCULAR HARM?

Many animal and clinical studies have established the physiologic actions on the heart and blood vessels of the vagus and sympathetic nerves, catecholamines, and sympathomimetic amines like ephedra and ephedrine, as well as the actions of caffeine. No controversy exists about the physiologic actions of these drugs. The major issue under discussion is whether these ephedra/caffeine combinations have pathophysiologic actions, that is, can they cause bodily harm. Information to support the latter comes mostly from adverse event reports (AERs) and case reports, which are not as “robust” as clinical studies. Still, more than 1200 serious reactions related to ephedra have been reported to the FDA, and it is suspected that the actual number of events is undoubtedly far greater due to the under-reporting noted earlier.⁷ These include strokes, arrhythmias, myocardial infarction, psychosis, and death.^{8,9} Apparently, 13,000 complaints have been registered with the manufacturer of Metabolife 356, including several hundred patients who required hospitalization and 80 incidents of serious injury or death.¹⁰ Canadian authorities have requested the voluntary recall of health products containing ephedra, noting its enhanced toxicity when combined with caffeine.¹¹

The reason for relying on AER and case report data is due to the relative infrequency of the adverse events. If a drug causes an adverse effect in only 1 of 1000 treated patients, then many patients have to be treated before a statistically significant result is noted. Such studies can be impossibly expensive to perform. And while information from AERs is less acceptable as proof of an effect, criteria can be applied to help establish validity. These include the following six criteria:

- 1) Temporal relation between taking the drug and the adverse response

- 2) Appropriate dose taken to have an effect
- 3) No other cause recognized to have produced the effect
- 4) Biologic plausibility, that is, the known action of the drug is consistent with the adverse response
- 5) De-and re-challenge, that is, stopping the drug eliminates further adverse responses, or re-starting the drug produces the same adverse response
- 6) Similar supportive data in published medical literature

Most of the reports on ephedra/caffeine compounds meet all six of these criteria. Some examples follow.

The report by Haller and Benowitz applied reasoning similar to the above 6 criteria in evaluating 140 AER reports submitted to the FDA between June 1997 and March 1998 and considered that 31% were definitely related to supplements containing ephedra and 31% possibly related. Ten events resulted in death and 13 produced a disability, representing 26% of the definite/probable and possible cases. Palpitations or tachycardia (rapid heart beat) occurred in 13.

Samenuk et al⁹ analyzed 37 patients from 926 cases of possible ma huang toxicity reported to the FDA between 1995 and 1997 and found that the compound was temporally related to stroke, heart attack, and sudden death at the normally taken doses in 36 of 37 people.

Gardner et al¹² treated 10 healthy men with 2 Metabolife 356 caplets (12 ephedra and 40mg caffeine in each) 3 times daily for 2 weeks and found that at day 3, all subjects reported adverse effects, most commonly dry mouth, shakiness and insomnia. Two men reported chest pain, two had large numbers of premature atrial beats and one had a 3 beat run of ventricular tachycardia.

AERs were noted in an 8 week controlled prospective weight loss study of 72 mg/day ephedrine and 240 mg/day caffeine.¹³ Boozer et al noted systolic pressure (4mm Hg) and heart rate (7 bpm) were higher in the ephedra group. One of thirty-five subjects left the study early due to elevated blood pressure and four due to palpitations with (1) or without (3) chest pain. Four additional subjects left the study after week 2 due to increased blood pressure, palpitations or extreme irritability. None left the study in the placebo group because of side effects. In a later 6-month study, Boozer¹⁴ found treated patients had increases in heart rate (4 bpm), blood pressure (3-5 mm Hg), dry mouth, insomnia, and heartburn.

An important recent review of the relative safety of ephedra products analyzed the number of adverse reactions adjudicated by poison control centers in the US in 2001 to be attributable to several commonly used herbal products. They found that products containing ephedra alone or combined with other herbs or substances accounted for 64% of all adverse reactions, yet these products represented only 0.82% of herbal sales. The relative risks for adverse reactions among ephedra users were 100-fold greater than the risk among users of other herbal products.¹⁵

A comprehensive literature review of 59 articles that corresponded to 52 controlled clinical trials of ephedrine or herbal ephedra for weight loss or athletic performance found that short term use was associated with approximately 2 pounds weight loss per month compared with placebo. There was a modest effect on very short-term athletic performance. However, there was a two to three times increase in the risk of nausea, vomiting, psychiatric symptoms, autonomic hyperactivity, and palpitations. The number of individuals studied were insufficient to evaluate events with a risk of less than 1.0 per thousand.¹⁶

V. SUPPORTING INFORMATION

Supporting information about the potential harm of catecholamines and sympathomimetic agents can be found in multiple sources. For example, plasma norepinephrine concentration is independently related to the subsequent risk of mortality.¹⁷ Patients who have sustained ventricular arrhythmias have a selective increase in cardiac sympathetic activity.^{18,19} In addition, use of sympathomimetic drugs leads to increased risk of hospitalization for arrhythmias in patients with congestive heart failure.²⁰ Plasma norepinephrine predicts survival and cardiovascular events in patients with end-stage renal disease.²¹ Large stores of noradrenaline in the heart have been related to sudden death.²²

VI. WHAT CAN ACCOUNT FOR THE APPARENT UNPREDICTABLE SPORADIC EVENTS?

The following can explain the above individual reactions to recommended doses of ephedra/caffeine compounds:

- 1) Variable absorption occurs, so that the amount of drug in the body can vary from one person to the next.
- 2) Variability in active drug content of botanical, as shown by Gurley et al.²

- 3) Presence or absence of underlying disease or drugs. It is possible that patients with pre-existing conditions such as coronary disease or high blood pressure, or who are taking other drugs that may interact with the ephedra/caffeine compounds, are at increased risk for an adverse response.
- 4) Variability in electrolytes, particularly potassium that can predispose to the development of arrhythmias.
- 5) Herbal products may contain undeclared pharmaceuticals or heavy metals.
- 6) Genetic influences. There exist some patients with genetic changes in the autonomic nervous system that make them susceptible to large outpouring of catecholamines which could put them at risk of developing an arrhythmia, heart attack or stroke.^{23,24} Also, some patients have inherited electrical abnormalities that do not become manifest until triggered by an external source like a drug.²⁵ This drug could have totally benign actions in all other individuals without the inherited abnormality.

VII. EPHEDRA/CAFFEINE AND EXERCISE

Many ephedra products are marketed for sports nutrition or for weight loss. The directions for use suggest that they should be taken before exercise. During exercise, the oxygen requirements of the heart increase dramatically. If the oxygen supply falls behind the demands of the heart, such a response can trigger abnormal heart rhythms. Oxygen consumption of the heart is directly related to wall stress and heart rate, both of which increase during exercise. The effects of the ephedra/caffeine drugs exacerbate these responses. Serious arrhythmias can develop because of this constellation of events. As physicians, we know that humans are biologic organisms that are imperfect. Humans do not run with absolute precision like a Swiss watch. Slight variations in blood pressure, heart rate, and conduction of the heart's impulse can make a difference between having an arrhythmia that produces sudden death and not having one. These responses are often unpredictable. Numerous sport organizations, including the NCAA, NFL, and International Olympic Committee, prohibit the use of ephedra-containing products.¹⁵

VIII. RECOMMENDATIONS:

Because of our inability to predict who might have an adverse response to these drugs, because of their minimal (if any) therapeutic effect and because of the potential for major adverse responses, I would recommend the following:

- 1) Recognize that ephedra and ephedrine are drugs, not dietary supplements
- 2) Recognize that they are capable of provoking harm, including ventricular fibrillation and sudden death
- 3) Eliminate over-the-counter use based on minor proven benefit and potential for major harm
- 4) Regulate their use by applying FDA criteria to distribution of ephedra/caffeine compounds as is done for all other drugs

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Mr. GREENWOOD. Thank you, Dr. Zipes and your very excellent presentation. I appreciate that.
Dr. Culmo?

TESTIMONY OF CYNTHIA CULMO

Ms. CULMO. Good morning.

Thank you, Mr. Chairman, Honorable Representative Greenwood and the committee members and Congresswoman Davis for this opportunity to participate in this important and critical discussion.

I appreciate the honor, but I would be remiss not to mention or point out that I do not have a doctorate degree so Ms. is the appropriate salutation.

I have served as the previous Director for Drugs and Medical Devices for the Texas Department of Health and the chairperson for the Drugs, Devices and Cosmetics Committee for the Association for Food and Drug Officials. And I still serve as a member of the United States Pharmacopeia Expert Panel for Dietary Supplement Information.

My comments are based upon my knowledge and experience in these positions for the last 12 years, and as an expert witness in civil lawsuits with dietary supplement companies.

I have no financial interest with this issue.

A primary premise of DSHEA is that dietary supplements are assumed to be safe for consumption and beneficial to health. I do not believe that these products do or can meet that safety assumption. I'll summarize my most concerning points.

There have been more serious adverse event reports for dietary supplements containing ephedra alkaloids than for any other type

of dietary supplement, or the OTC, over-the-counter phenylpropanolamine drug products which were withdrawn from the U.S. markets last year due to the increased risk of hemorrhagic stroke in young women. The serious adverse events have already been discussed by everyone here. They are known, documented and expected consequences of the use of ephedrine.

Pharmacologically in the body there is no difference between natural and synthetic ephedrine. They act the same in the body. By regulation drug products containing ephedrine cannot be combined with any other stimulate based upon the potential for abuse and safety concerns. Not so for dietary supplements.

Currently marketed dietary supplements for enhanced athletic performance, increased energy and weight loss don't just contain ephedrine. Almost all of the multi-ingredient products contain ephedrine with other stimulants, diuretics, laxatives and other active ingredients. These multi-ingredients can interact with each other and other products, drugs and/or foods and they have well known counter-indications as well as documented and well known drug disease interactions. Studies identifying these complex interactions which have definite effect on the safety of these products are available.

The United States has developed a rigorous and widely emulated system for evaluation and approval of new drugs. The United States, however, did not emulate countries such as Japan and Germany which accommodated national traditions by developing special regulations for traditional medicines and dietary supplements in general.

In Europe the European Union is developing specific regulations on botanical products under the drug system. The EU directives regulate the manufacturing, the distribution, the marketing and approval of herbal products in addition to requirements for post-market surveillance.

Although the industry routinely claims that their products are not drugs, they are posed to the consumer as drug products by their claims, the manner in which they are advertised, the way the information is shared by health professionals, which some are sold by these health professionals and doctors, and they are advertised the infamous PDR, the Physicians Desk Reference; all of which can mislead the consumer.

Many of the studies the industry uses to support safety came from foreign data for prescription drugs using pharmaceutical ephedrine and caffeine. These products are not the same. None of these studies can be used to support the safety of dietary supplements. Recently the Danish government withdrew the prescription drug Letigen. This is the product that the Astrup studies utilized and that the industry routinely references and bases the safety and efficacy of these products on.

Also note, it is a product that has only two active ingredients in it. Nothing like the multi-ingredient products in the United States. Letigen is an ephedrine caffeine weight loss product removed from the market due to the same types of adverse events reports FDA has received on ephedrine containing dietary supplements.

There are numerous methodology problems with a relatively few studies in the United States, including being too small, not using

marketed products, the infamous Boozer 6 month study did not use Metabolife 356. So the results of these studies cannot be applied to the general population for efficacy, much less safety. Companies always say in report, especially to the media and you will probably hear it in this hearing today, that billions of doses of ephedra have been used safely. Everyone needs to remember that these are doses sold, maybe, not consumed. This is another example of false and misleading information.

DSHEA shifted the requirement of proving a product is unsafe to the government. Many States have had to pick up this tremendous burden because of the apparent inability of the Federal Government to effectively address safety issues associated with these products. Under DSHEA safety is addressed after harm has already occurred. The standards and the criteria of safety have never been defined by FDA or the court.

A major question yet to be answered is what is questionable or unreasonable risk that causes a product to be adulterated? The most egregious safety problems with a dietary supplement for enhanced performance, increased energy and weight loss right now, obviously, are products containing ephedrine. The situation is not a scientific issue any longer. It is a political issue run by a political agenda. There are ongoing conflicts between good public health and the industry's economic needs with politics frequently serving as the referee.

Consumers are being misled and they are not getting the full story about the risk associated with these products. They cannot make an informed decision about appropriate use. Labeling and warnings cannot solve the safety issues. The warnings and the labels will not help when you do not know that you have a condition that places you at increased risk.

A firm which has recently been sued is using the defense that the victim was overweight and out of shape. Where do any of these products say that being overweight, exercising which is usually recommended and taking these products are dangerous?

In the past the States have indicated and continue to experience numerous problems associated with dietary supplements with ephedrine and have recommended a number of solutions:

Except for traditional nutrients such as vitamins and minerals prohibit or limit botanicals and other natural products to a single ingredient. This is what Health Canada has done with ephedra. If you are going to be taking combination products as a dietary supplement, then they should be required to have pre-market review for safety.

Require the manufacturers and the distributors to register with FDA and list their products and ingredients. This is going to be one of the requirements due to bioterrorism now. But this will enable FDA to develop appropriate product data bases to evaluate products, adverse event reports and their interactions.

Institute mandatory adverse event reports. Analogous to what is required for drugs, biologics and medical devices. These are active ingredients and they should be treated as such, otherwise why are not these studies being done by the companies in an effort to somewhat substantiate their efficacy claims?

Implement an integrated adverse event reporting system within the FDA. Adverse event report, evaluation and risk management is best directed by regulatory agencies.

Define the criteria for DSHEA, the standard of significant or unreasonable risk. What is the standard to prove that a product is safe? From a science perspective if what is currently known about ephedra supplements and cannot meet the standard, what in the world will?

Create a specific center within FDA for traditional medicines and dietary supplements for regulatory oversight, and appropriate funding and improve authority to the FDA is necessary for all of the above.

In conclusion, I appreciate this opportunity to provide you with my comments. It's tragic that once again deaths have had to occur to bring this topic one more time to the forefront for discussion. Hopefully, this time actions will be taken and other unsuspecting victims will be spared.

I have no doubt that products currently marketed dietary supplements for increased energy, improved athletic performance and weight loss purposes are either not safe or of unknown safety and the public health is not being adequately protected. I believe that a total ban of these products is the only ethically acceptable public health solution. Warnings and dosage and ingredient limitations are not going to address this public health risk.

This is simple. How many more bodies does it take? I would agree with Dr. Woosley, no more studies, no more labeling requirements. The FDA is neglecting its duties and responsibilities to protect the public health. Public health decisions should not be allowed to be ruled by politics or by referring scientific decisions to the court. It is time to place the politics and the money aside at the Federal level and act as the responsible public health agency that the general public considers the FDA to be and to which it is charged.

You the politicians must, too, be responsible and support this charge for the public, your constituents.

Thank you very much.

Mr. GREENWOOD. Thank you, Ms. Culmo. We appreciate your testimony very much.

Dr. Crosse?

TESTIMONY OF MARCIA CROSSE

Ms. CROSSE. Yes, Mr. Chairman, members of the subcommittee and Representative Davis, I am pleased to have the opportunity to testify as the subcommittee considers dietary supplements that contain ephedra.

Reports of adverse health events associated with such supplements, including reports of heart attacks, strokes, seizure and death have been received by FDA and others including Metabolife International, the manufacturer of a dietary supplement containing ephedra, Metabolife 356. Because of concerns surrounding the marketing and use of supplements containing ephedra you asked us to examine FDA's analysis of adverse events reports it has received about such supplements, how the adverse events reported to Metabolife International illustrate the health risks of dietary sup-

plements containing ephedra, and FDA's actions in the oversight of such supplements.

Because dietary supplements are generally marketed without prior FDA review of their safety, FDA relies on voluntary reports of adverse events from consumers, health professionals, manufacturers and others in its efforts to oversee the safety of marketed dietary supplements. Based on over 2000 adverse event reports it has received on supplements containing ephedra, FDA has determined that such supplements pose a significant public health hazard. The number of adverse event reports FDA has received for dietary supplements containing ephedra is 15 times greater than the number it has received for the next most commonly reported herbal dietary supplement.

While it is difficult to establish with certainty that a particular adverse event has been caused by the use of ephedra, based on the pattern of adverse event reports it has received and the scientific literature it has reviewed, FDA has concluded that ephedra poses a risk of cardiovascular and nervous system effects among consumers who are young to middle-aged.

In our review of health related call records from Metabolife International, we identified adverse events that were consistent with the types of adverse events reported to FDA and with the documented physiological effects of ephedra. We identified over 14,000 call records that contained reports of at least one adverse event among consumers of Metabolife 356. Among these were 92 serious events—heart attacks, strokes, seizures and deaths—and over 1,000 events of the types that FDA has identified as serious or potentially serious including chest pain and significant elevations in blood pressure.

Many of the serious events were among relatively young consumers. More than one-third concerned consumers who were under age 30.

In addition, we found that most of the serious adverse events occurred among consumers who followed the usage guidelines on the Metabolife 356 label. The consumers did not take more of the product or take it for a longer period than the company recommended.

FDA has taken some actions specifically focused on dietary supplements containing ephedra, as we have heard about. The agency has issued warnings to manufacturers that focus on improper labeling and issued warnings to consumers, particularly about dietary supplements that contain both ephedra and stimulants such as caffeine.

In 1997 FDA issued a proposed rule that, among other things, would require a health warning on the label and prohibit a supplement from containing both ephedra and a stimulant. This rule has not been finalized and many dietary supplements that contain both ephedra and stimulant ingredients including Metabolife 356 continue to be marketed. In the meantime, FDA has banned over-the-counter drugs that contain such combinations.

In summary, Mr. Chairman, significant concerns have been identified regarding dietary supplements that contain ephedra. Because the regulatory framework for dietary supplements is primarily a post-marketing program and FDA does not review the safety of dietary supplements before they are marketed, adverse event reports

are important sources of information about the health risks of dietary supplements containing ephedra. The adverse event reports FDA received for dietary supplements containing ephedra and the consistency of those reports with the scientific literature led the agency to conclude 3 years ago that these supplements pose a significant public health hazard. It is, therefore, important that FDA move forward quickly in determining what further actions are warranted.

Mr. Chairman, this completed my prepared statement. I would be happy to answer any questions you or other members may have. [The prepared statement of Marcia Crosse follows:]

PREPARED STATEMENT OF MARCIA CROSSE, ACTING DIRECTOR, HEALTH CARE-PUBLIC HEALTH AND SCIENCE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today as the Subcommittee considers concerns about the safety of dietary supplements containing ephedra. More than half of U.S. adults are overweight or obese, and more than one-third are trying to lose weight. Many Americans have turned to dietary supplements to help them lose weight. The most widely used weight loss supplement ingredient is ephedra, which is also referred to as *ma huang*.¹ The dietary supplement industry has estimated that as many as 3 billion servings of dietary supplements containing ephedra are consumed each year in the United States. Medical experts have expressed concerns about the safety of dietary supplements containing ephedra. Reports of adverse health events associated with such supplements, including reports of heart attack, stroke, seizure, and death, have been received by the Food and Drug Administration (FDA) and others, including Metabolife International, the manufacturer of a dietary supplement containing ephedra, Metabolife 356.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) created a framework for FDA's regulation of dietary supplements as part of its oversight of food safety.² Since dietary supplements are generally marketed without prior FDA review of their safety, FDA relies on voluntary reports of adverse events from consumers, health professionals, manufacturers, and others in its effort to oversee the safety of marketed dietary supplements.

Because of concerns surrounding the safety of dietary supplements containing ephedra, you asked us to discuss some of the findings from our prior work on ephedra. My remarks today will focus on (1) FDA's analysis of adverse event reports it has received about dietary supplements containing ephedra, (2) how the adverse events reported in the call records received by Metabolife International illustrate the health risks of dietary supplements containing ephedra, and (3) FDA's actions in the oversight of dietary supplements containing ephedra.

This testimony is based primarily on our earlier reports on dietary supplements, including our March 2003 review of health-related call records received by Metabolife International.³ For this testimony, we also conducted additional analyses of the data in the Metabolife International call records, obtained updated information from FDA about its oversight efforts and adverse event reports that it has received concerning ephedra, and reviewed FDA analyses of the safety of dietary supplements containing ephedra. We conducted our work from June 2003 through July 2003 in accordance with generally accepted government auditing standards.

In summary, FDA has determined that dietary supplements containing ephedra pose a significant public health hazard based on the 2,277 adverse events reports it has received. The number of adverse event reports FDA has received for dietary supplements containing ephedra is 15 times greater than the number it has received

¹ The active ingredients in ephedra are ephedrine alkaloids. Ephedrine alkaloids that are not from an herbal or botanical source (or a derivative thereof), such as synthetic ephedrine alkaloids, may not be marketed as dietary supplements.

² Pub. L. No. 103-417, 108 Stat. 4325.

³ U.S. General Accounting Office, Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids, GAO/HEHS/GGD-99-90 (Washington, D.C.: July 2, 1999); Health Products for Seniors: "Anti-Aging" Products Pose Potential for Physical and Economic Harm, GAO-01-1129 (Washington, D.C.: Sept. 7, 2001); Dietary Supplements for Weight Loss: Limited Federal Oversight Has Focused More on Marketing Than on Safety, GAO-985T (Washington, D.C.: July 31, 2002); and Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356, GAO-03-494 (Washington, D.C.: Mar. 31, 2003).

for the next most commonly reported herbal dietary supplement. While it is difficult to establish with certainty that a particular adverse event has been caused by the use of ephedra, based on the pattern of adverse event reports it has received and the scientific literature it has reviewed, FDA has concluded that ephedra poses a risk of cardiovascular and nervous system effects among consumers who are young to middle-aged.

The types of adverse events that we identified in the health-related call records from Metabolife International were consistent with the types of adverse events reported to FDA and with the documented physiological effects of ephedra. Although the call records contained limited information for most of the reports, we identified 14,684 call records that contained reports of at least one adverse event among consumers of Metabolife 356. Our count of 92 serious events—heart attacks, strokes, seizures, and deaths—was similar to that of other reviews of the call records, including counts by Metabolife International and its consultants. Many of the serious events were reported among relatively young consumers—more than one-third concerned consumers who reported an age under 30. In addition, for the call records containing information on the amount of product consumed or length of product use, we found that most of the reported serious adverse events occurred among consumers who followed the usage guidelines on the Metabolife 356 label—the consumers reported that they did not take more of the product or take it for a longer period than the company recommended.

As part of its oversight of dietary supplements, FDA has taken some actions specifically focused on dietary supplements containing ephedra. FDA has issued warnings to manufacturers that focus on improper product labeling, issued warnings to consumers, and issued a proposed rule in 1997 that, among other things, would require a health warning on the label of dietary supplements containing ephedra and prohibit a dietary supplement from containing both ephedrine alkaloids—the active ingredient in ephedra—and a stimulant. FDA subsequently banned the sale of certain classes of over-the-counter drugs containing ephedrine and related alkaloids in combination with an analgesic or stimulant. As the 1997 proposed rule has not been finalized, there is no rule prohibiting the marketing of dietary supplements with similar ingredients, and many dietary supplements with ephedra, such as Metabolife 356, also include caffeine or other stimulants. To receive comments on new evidence, FDA recently reopened the comment period for the proposed rule, and FDA reported to us that the agency is in the process of reviewing comments it has received and has not reached a decision regarding further action.

BACKGROUND

Ephedra, the most widely used ingredient in dietary supplements for weight loss, is a powerful stimulant that can affect the nervous and cardiovascular systems. Adverse events among consumers of dietary supplements containing ephedra have been described in scientific literature and in detailed adverse event reports. Because of concerns about the risks of ephedra, medical organizations, states, and athletic associations have sought to reduce the use of dietary supplements containing ephedra.

FDA Oversight of Dietary Supplements under DSHEA

Under DSHEA, FDA regulates dietary supplements, including vitamins, minerals, herbs and other botanicals, amino acids, certain other dietary substances, and derivatives of these items. DSHEA requires that dietary supplement labels include a complete list of ingredients and the amount of each ingredient in the product.⁴ Dietary supplements may not contain synthetic active ingredients that are sold in over-the-counter drugs and prescription medications and cannot be promoted as a treatment, prevention, or cure for a specific disease or condition.

Under DSHEA, manufacturers are responsible for ensuring the safety of dietary supplements they sell. Dietary supplements do not need approval from FDA before they are marketed; thus FDA generally addresses safety concerns only after dietary supplements are marketed. DSHEA does not require manufacturers to register with FDA,⁵ identify the products they manufacture, or provide reports of adverse events

⁴Products may include “proprietary blends,” which must list all ingredients but do not need to list the amount of each ingredient.

⁵However, manufacturers and distributors of dietary supplements are required to register with FDA no later than December 13, 2003, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594. FDA issued a proposed rule in February 2003 to implement the requirement. See 68 *Fed. Reg.* 5378 (Feb. 3, 2003).

to FDA. Mechanisms that FDA uses to oversee dietary supplements and other products it regulates differ (see app. I for more details).

Since manufacturers of dietary supplements are not required to provide reports of adverse events to FDA, the agency relies on voluntary postmarket reporting of adverse events to better understand the safety of dietary supplements. Some individual adverse event reports are especially valuable to FDA because they include enough information to help FDA determine if the adverse event was likely caused by the supplement. These reports include information about the receipt of medical care, health care professionals' attribution of adverse events to the consumption of dietary supplements, the consumer's appropriate use of the products, the consumer's use of other products, underlying health conditions and other alternative explanations for the adverse event, and the consistency of symptoms with the documented effects of the dietary supplement.

FDA, through the Department of Justice, can take enforcement action in court against dietary supplements that are adulterated to remove them from the market.⁶ A dietary supplement is considered adulterated under a number of circumstances, including when it

- presents a "significant or unreasonable risk of illness or injury" under the conditions of use recommended or suggested in its labeling, or under ordinary conditions of use if there are no suggestions or recommendations in the labeling, or
- bears or contains any "poisonous or deleterious substance" which may render it injurious to health under the conditions of use recommended or suggested in its labeling.

Instead of going to court, FDA may choose to take administrative action to prohibit the sale of dietary supplements it considers to be adulterated. FDA can promulgate a regulation declaring a particular dietary supplement to be adulterated. FDA has not taken this action with any dietary supplement. FDA can also issue an advisory letter explaining why it considers the dietary supplement to be adulterated. The advisory letter provides guidance to the industry regarding FDA's opinion and notifies the public that FDA may take legal action against firms or individuals that do not follow the letter's advice. FDA has done this for two dietary supplement ingredients, comfrey and aristolochic acid.

In addition, although it has never been done, the Secretary of Health and Human Services (HHS) may declare that a dietary supplement is adulterated because it poses an "imminent hazard" to public health or safety. In doing so, the Secretary must initiate an administrative hearing to affirm or withdraw the declaration.

Health Concerns about Ephedra

Ephedra has been associated with numerous adverse health effects. As we previously reported,⁷ case reports and scientific literature have suggested that ephedrine alkaloids can increase blood pressure in those with normal blood pressure, predispose certain individuals to rapid heart rate, and cause stroke, among other things. We also reported descriptions of adverse events associated with ephedrine alkaloids that affected the central nervous system, such as seizures, mania, and paranoid psychoses. FDA has received reports of adverse events associated with dietary supplements containing ephedra, including heart attack, stroke, seizure, psychosis, and death, that are consistent with the scientific literature. In February 2003, the RAND Corporation released a review of the scientific evidence on the safety and efficacy of dietary supplements containing ephedra⁸ and concluded that a sufficient number of cases of these same types of events had occurred in young adults to warrant further scientific study of the causal relationship between ephedra and these serious adverse events. RAND also found that use of ephedra or ephedrine plus caffeine is associated with a number of other adverse effects, including an increased risk of nausea, vomiting, heart palpitations, and psychiatric symptoms such as anxiety and change in mood.

Because of these health concerns, many organizations and jurisdictions have taken actions aimed at reducing the use of dietary supplements containing ephedra. The American Medical Association and the American Heart Association have urged FDA to ban the sale of dietary supplements containing ephedra. In January 2002,

⁶"Adulterated" is the statutory term used to describe dietary supplements and other FDA-regulated products that are unsuitable for marketing. It is illegal to market any adulterated product.

⁷GAO/HEHS/GGD-99-90.

⁸Paul Shekelle, et al., *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. Evidence Report/Technology Assessment No. 76 (prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290-97-0001, Task Order No. 9). AHRQ Publication No. 03-E022 (Rockville, Md.: Agency for Healthcare Research and Quality, February 2003).

Health Canada issued a Health Advisory for Canadians not to use certain products containing ephedra, especially those that also contain caffeine and other stimulants. In 2003, Illinois banned the sale of products containing ephedra and other states have similar bans under consideration. In addition, some states have banned the sale of such products to minors or required label warnings. Several sports organizations, including the NCAA, the National Football League, the U.S. Olympic Committee, and the International Olympic Committee, have banned the use of ephedra by their athletes.

In 2003, General Nutrition Centers, the nation's largest specialty retailer of nutritional supplements, discontinued the sale of products containing ephedra, as have three other major retail outlets. Some manufacturers have stopped producing dietary supplements containing ephedra. Other manufacturers continue to offer dietary supplements containing ephedra while also offering similar products that are ephedra-free.⁹

ADVERSE EVENT REPORTS HAVE LED FDA TO CONCLUDE THAT DIETARY SUPPLEMENTS
CONTAINING EPHEDRA POSE A SIGNIFICANT PUBLIC HEALTH HAZARD

Using the adverse event reports it has received and evidence from the scientific literature, FDA has concluded that dietary supplements containing ephedra pose a "significant public health hazard." FDA and others have received thousands of reports of adverse events among users of dietary supplements containing ephedra, more than for any other dietary supplement ingredient. Metabolife International also received thousands of reports of adverse events.

More Adverse Events Have Been Reported for Products Containing Ephedra Than for Any Other Dietary Supplement

FDA has received more reports of adverse events for dietary supplements containing ephedra than for any other dietary supplement ingredient. In addition, poison control centers and one manufacturer, Metabolife International, have received thousands of reports of adverse events associated with dietary supplements containing ephedra. From February 22, 1993, through July 14, 2003, FDA received 2,277 reports of adverse events associated with dietary supplements containing ephedra, which was 15 times more reports than it received for the next most commonly reported herbal dietary supplement, St. John's wort.¹⁰

Other organizations also have received a large number of adverse event reports for dietary supplements containing ephedra. The American Association of Poison Control Centers received 1,428 reports of adverse events associated with dietary supplements containing ephedra, either alone or in combination with other botanical dietary supplement ingredients, in 2002,¹¹ nearly two-thirds as many as FDA received over a 10-year period. The centers noted that there were more reports of adverse events for ephedra-containing dietary supplements than for others. Further, as we reported in March 2003, Metabolife International had 14,684 health-related call records that contained reports of adverse events associated with its product, Metabolife 356, from May 1997 through July 2002.¹² Neither the American Association of Poison Control Centers nor Metabolife International is required to report these adverse events to FDA.

FDA Has Determined That the Adverse Event Reports and Scientific Literature Indicate That Dietary Supplements Containing Ephedra Pose a Significant Public Health Hazard

From the adverse event reports it has received and the scientific literature it has reviewed, FDA concluded in March 2000 that dietary supplements containing ephedra pose a significant public health hazard that primarily involves consumers who are young to middle-aged and can result in adverse cardiovascular and nervous

⁹Some ephedra-free products include other herbal stimulants, such as *Citrus aurantium*. *Citrus aurantium* contains synephrine, which is chemically similar to the ephedrine and pseudoephedrine found in many over-the-counter and allergy medicines and in dietary supplements containing ephedra.

¹⁰In total, FDA received 5,574 adverse reports for dietary supplements during that period. The total number of reports of adverse events for ephedra products includes 135 reports from the Metabolife International call records that FDA designated as serious adverse events.

¹¹William A. Watson, et al., "2002 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System," *American Journal of Emergency Medicine* (in press). See also Stephen Bent, et al., "The Relative Safety of Ephedra Compared with Other Herbal Products," *Annals of Internal Medicine*, vol. 138 (2003), 468-471.

¹²GAO-03-494.

system effects.¹³ It further concluded that many of the adverse events were serious, resulting in morbidity and mortality that would not be expected in a young population and that could further compromise the health of more vulnerable older adults or those with underlying conditions.

A study commissioned by FDA estimated that the agency receives reports for less than 1 percent of adverse events associated with dietary supplements.¹⁴ Although causality cannot be determined based on the individual adverse event reports FDA receives, the agency uses these reports to identify possible risks to consumers from dietary supplements. As we have previously reported, there are well-known weaknesses in the current system of voluntary reporting of adverse events, such as different interpretations in determining an adverse event, underreporting, difficulties estimating population exposure, and poor report quality.¹⁵ Despite these limitations, FDA maintains that even isolated reports can be definitive in associating products with an adverse effect if the report contains sufficient evidence, such as supporting medical documents, a temporal relationship between the product and effect, and evidence of dechallenge and rechallenge.¹⁶

METABOLIFE INTERNATIONAL CALL RECORDS CONTAIN REPORTS OF ADVERSE EVENTS
THAT ARE CONSISTENT WITH THE TYPES OF ADVERSE EVENTS REPORTED TO FDA

The types of adverse events that we identified in the Metabolife International call records are consistent with the types of adverse events reported to FDA and with the documented physiological effects of ephedra. As we recently reported, most of the Metabolife International call records contained limited information about the event and the consumer. Nonetheless, the call records contribute to existing knowledge about adverse events that have been associated with ephedra use. In our review, we identified 14,684 call records that contained reports of at least one adverse event among consumers of Metabolife 356. Within these call records, we found 92 reports of serious adverse events—heart attacks, strokes, seizures, and deaths—a count that was similar to that of other reviews of the call records. In addition, the call records contain reports of serious adverse events in consumers who were young and among those who used the product within the recommended guidelines. These findings are consistent with reports FDA has received regarding dietary supplements containing ephedra.

Consumer Information in the Metabolife International Call Records Was Limited

In our review of health-related call records for users of Metabolife 356,¹⁷ we found that the information in the call records was limited. Call records were sometimes difficult to read and interpret, and consumer information was not consistently recorded. In some cases, the evidence for a report of an adverse event was limited to a single word on a call record. In other cases, information was entered into a form developed by Metabolife International with multiple boxes for consumer- and event-related information. Most call records did not document complete information about the consumer's age, sex, weight, and height. Because the company did not systematically follow up on calls reporting adverse events, and the adverse events were not reported to FDA, it is not possible to gather more complete information or medical records.

METABOLIFE INTERNATIONAL CALL RECORDS CONTAINED REPORTS OF THOUSANDS OF
ADVERSE EVENTS, SOME OF WHICH WERE SERIOUS, AMONG CONSUMERS OF
METABOLIFE 356

As we reported in March 2003, we identified 14,684 call records that contained at least one report of an adverse event among consumers of Metabolife 356.¹⁸ The types of reported adverse events were consistent with the cardiovascular and central nervous system effects that have been associated with ephedra products in the literature, adverse event reports received by FDA, other case reports, and RAND's review. Within the call records, we identified 92 reports of heart attack, stroke, sei-

¹³ Food and Drug Administration, *Assessment of Public Health Risks Associated with the Use of Ephedrine Alkaloid-containing Dietary Supplements* (Mar. 31, 2000) (Docket No. 00N-1200).

¹⁴ U.S. Department of Health and Human Services, Office of Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve*, OEI-01-00-00180 (Washington, D.C.: Apr. 2001).

¹⁵ GAO/HEH/GGD-99-90.

¹⁶ Dechallenge is evident when signs and symptoms resolve or improve when a consumer stops using a product, and rechallenge is evident when symptoms recur when the consumer resumes using the product.

¹⁷ GAO-03-494.

¹⁸ A single call record may have had more than one complaint.

zure, and death (see table 1).¹⁹ Our count of reports of these serious adverse events was similar to that of other reviews of the Metabolife International call records, including counts by Metabolife International and its consultants.²⁰

Table 1: Number of Reports of Heart Attack, Stroke, Seizure, or Death in Metabolife International Call Records

Type of adverse event	Number ¹
Heart attack	18
Stroke	26
Seizure	43
Death	5

Source: Metabolife International.

Note: GAO analysis of 14,684 health-related call records provided by Metabolife International.

¹The counts do not represent unique consumers because a single call record may have more than one complaint and because some consumers called the Metabolife health information phone line more than once.

We also found 1,079 reports of other types of adverse events that FDA identified as serious or potentially serious.²¹ These included chest pain, significant elevations in blood pressure, systemic rash, and urinary infection. In addition to these 1,079 reports, we found records that contained reports of a broad range of other types of adverse events, including changes in heart rate such as palpitations and increased heart rate; blood in stool; blood in urine; bruising; hair loss; and menstrual irregularity.²²

Reports of Serious Adverse Events Involved Consumers Who Were Relatively Young

Within the subset of call records that contained information on age, the distribution of ages suggests that a relatively young population was experiencing the reported serious adverse events. Among the call records that contained a report of a serious event, 44 percent included information on age.²³ For these call records, more than one-third concerned consumers who reported an age under 30—the average reported age was 38 (ranging from 17 to 65). As noted above, FDA has also received reports of serious adverse events occurring in a population of young adults. Because we do not know the age profile of all Metabolife 356 consumers, we cannot determine if the age distribution among those reporting serious adverse events in the Metabolife International call records reflects that age profile.

Serious Adverse Events Were Reported among Consumers Who Used Metabolife 356 within Recommended Guidelines

Within the subset of Metabolife International call records that contained information on how the product was used by the consumer, most of the reported serious adverse events occurred among consumers who reported using the product within the guidelines on the Metabolife 356 label—that is, who reported that they did not take more of the product or take it for a longer period than recommended.²⁴ Information about product use, however, was incomplete—40 and 55 percent of the call records that reported a serious event contained information about the amount of Metabolife 356 used and the duration of use, respectively. Among the call records

¹⁹We highlighted these serious adverse events because they are identified in FDA's proposed label warning for dietary supplements containing ephedra. See 68 Fed. Reg. 10417 (Mar. 5, 2003).

²⁰Metabolife International has not issued a report on its review of the call records, but provided us with a list of the calls it believed to report heart attack, stroke, seizure, and death. Metabolife International also commissioned reviews by three consultants (see GAO-03-494).

²¹In its 1997 proposed rule on dietary supplements containing ephedra, FDA identified as serious or potentially serious some types of adverse events for which the agency had received reports. See 62 Fed. Reg. 30678 (June 4, 1997).

²²Within the complete set of call records, we also found 332 reports of visits to either an emergency department or a hospital. According to FDA officials, unlike most adverse events related to foods, adverse event reports it had received related to ephedra products commonly involved a visit to a physician or an emergency room. FDA considers a hospitalization or prolongation of an existing hospitalization to be a serious adverse event. Metabolife International records did not consistently distinguish between an actual hospitalization and "going to the hospital," which may not have resulted in an actual hospitalization.

²³For the entire set of the Metabolife International call records, 42 percent contained information on the age of the consumer.

²⁴The product label recommends that adults take one to two caplets two to three times per day or every 4 hours, not to exceed eight caplets per day. The label also recommends that persons should not use the product for more than 12 weeks and that exceeding the recommended amount may cause serious adverse health effects, including heart attack or stroke.

that reported a serious adverse event and also contained information about product use, 97 percent of consumers reported using an amount of product within the recommended guidelines. Similarly, 71 percent of those consumers reported using the product for a length of time that was within the recommended guidelines.²⁵ This pattern is consistent with findings from FDA's review of adverse events associated with ephedra products.²⁶

FDA HAS TAKEN SOME ACTIONS TO OVERSEE DIETARY SUPPLEMENTS CONTAINING EPHEDRA

As part of its oversight of dietary supplements, FDA has taken some actions specifically focused on dietary supplements containing ephedra. FDA has issued warnings that focus on improper product labeling, issued warnings to consumers, and issued a proposed rule in 1997 that, among other things, would require a health warning on the label of dietary supplements containing ephedra and prohibit a dietary supplement from containing both ephedra and a stimulant. However, parts of this rule remain under consideration 6 years after it was first proposed.

As we previously reported, FDA has focused its enforcement actions regarding dietary supplements on improper labeling.²⁷ For example, in February 2003, FDA issued warning letters to 26 firms that sell dietary supplements containing ephedra. All of these letters advised marketers that label claims for enhancement of physical performance were unsubstantiated and the products were therefore misbranded.

FDA and HHS have also directly warned consumers about the safety of dietary supplements containing ephedra. In February 1995, FDA issued a press release warning consumers about a specific dietary supplement product that contained both ephedra and caffeine, because it had determined that the product represented a threat to public health. Further, in February 2003, the Secretary of HHS issued a statement to caution people against using dietary supplements containing ephedra and indicated that FDA continues to have serious concerns about the risks of these dietary supplements.

FDA has also taken actions in its oversight of dietary supplements in general. Specifically, FDA has conducted facility inspections²⁸ and proposed good manufacturing practice (GMP) regulations²⁹ that focus on product quality in general, not the safety of an individual ingredient.

FDA first issued a proposed rule to regulate dietary supplements containing ephedrine alkaloids in 1997.³⁰ The proposed rule would

- define the amount of ephedrine alkaloids in a serving of dietary supplement at and above which the product would be deemed adulterated (8 milligrams),
- establish labeling requirements regarding maximum frequency of use and daily serving limits,
- require that labels on these supplements contain a statement warning that the product should not be used for more than 7 days,
- prohibit the use of ephedrine alkaloids with ingredients that have a known stimulant effect (e.g., caffeine),
- prohibit labeling claims that promote long-term intake of the supplements to achieve the purported purpose,
- require a warning statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect, and
- require that specific warning statements appear on product labels.

Our 1999 report on the proposed rule was critical of the science FDA used to support the serving size and duration of use limits in the proposed rule.³¹ However, we did not conclude that dietary supplements containing ephedra were safe, and we commented that the adverse events reported to FDA were serious enough to war-

²⁵ For all call records containing information on the amount of product used or duration of use, 99 and 91 percent of consumers, respectively, reported using the product within the guidelines recommended on the label.

²⁶ Food and Drug Administration, March 2000.

²⁷ GAO-02-98-ST.

²⁸ Since 1999, FDA, its state partners, and state contractors have inspected 6 percent of the known dietary supplement manufacturing and repacking facilities annually. Inspections focus on sanitation, buildings and facilities, equipment, production, and process controls.

²⁹ In March 2003, FDA issued proposed GMP regulations for dietary ingredients and dietary supplements. See 68 *Fed. Reg.* 12158 (Mar. 13, 2003). The comment period for the proposed GMPs was extended until Aug. 11, 2003. See 68 *Fed. Reg.* 27008 (May 19, 2003). GMP regulations are important in ensuring that the product is not contaminated and contains what the label reports. They do not, however, address the safety of any individual ingredient, such as ephedra.

³⁰ 62 *Fed. Reg.* 30678 (June 4, 1997).

³¹ GAO/HEHS/GGD-99-90.

rant FDA's further investigation of ephedra safety. Primarily, we were concerned that FDA used only 13 adverse event reports to establish serving limits and had weak support for proposed limits on duration of use. Partly as a result of our review, FDA withdrew the sections of the proposed rule on serving size and duration of use limits.³²

In the interim, FDA has taken action to regulate certain drugs that contain ephedrine, the active ingredient in ephedra. In September 2001, FDA issued a final rule stating that certain over-the-counter drugs containing ephedrine and related alkaloids in combination with an analgesic or stimulant could not be marketed as over-the-counter drugs.³³ There currently is no similar rule prohibiting the marketing of dietary supplements containing ephedra in combination with analgesics or stimulants, such as caffeine. As a result, dietary supplements may contain ingredients that are prohibited in drugs. In fact, many dietary supplements with ephedra, such as Metabolife 356, also include caffeine. The proposed rule contains a provision that would prohibit dietary supplements from containing both ephedra and other stimulants.

In March 2003, almost 6 years after the initial proposal, FDA reopened the comment period for the remaining provisions of this proposed rule for 30 days.³⁴ FDA sought comments on three areas:

- New evidence on health risks associated with ephedra.
- Whether the currently available evidence and medical literature demonstrate that dietary supplements containing ephedra pose a "significant or unreasonable risk of illness or injury" under the conditions of use recommended or suggested in their labeling, or under ordinary conditions of use if there are no suggestions in the labeling.
- A new warning label for ephedra products that warns about reports of serious adverse events after the use of ephedra, including heart attack, seizure, stroke, and death; cautions that the risk can increase with the dose, with strenuous exercise, and with other stimulants such as caffeine; specifies certain groups (such as women who are pregnant or breast feeding and persons under 18) who should not use these products; and lists other diseases, such as heart disease and high blood pressure, that should rule out the use of ephedrine alkaloids.

On July 14, 2003, FDA reported to us that the agency is in the process of reviewing the comments and has not reached a decision regarding further action. While FDA has not attempted to ban the marketing of dietary supplements containing ephedra, the agency has sought, in these comments, additional information that would help it determine whether or not such action would be warranted.

CONCLUDING OBSERVATIONS

Because the regulatory framework for dietary supplements is primarily a post-marketing program and FDA does not review the safety of dietary supplements before they are marketed, adverse event reports are important sources of information about the health risks of dietary supplements containing ephedra. It is often difficult to demonstrate conclusively that a single reported adverse event was caused by ephedra, but some individual reports, particularly when they are complemented by follow-up investigation of the case, can be especially informative. Although the information in the Metabolife International call records we examined was limited, the types of adverse events we observed were consistent with the known risks of ephedra, including serious events such as five reports of death. Based on the pattern of adverse event reports FDA has received and the consistency of those reports with the known effects of ephedra from the scientific literature, the agency concluded 3 years ago that dietary supplements containing ephedra pose a "significant public health hazard." FDA is currently reviewing information that will help the agency determine what further actions are warranted.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

³² 65 *Fed. Reg.* 17474 (Apr. 3, 2000).

³³ See 66 *Fed. Reg.* 49276 (Sept. 27, 2001).

³⁴ 68 *Fed. Reg.* 10417 (Mar. 5, 2003).

Appendix I: Mechanisms for FDA Oversight of Different Types of Products

Product class	Product registration	Manufacturer registration	Pre-market approval of products	Specific good manufacturing practices	Voluntary postmarket adverse event reporting system	Mandatory manufacturer reporting of adverse events	Safety-related labeling requirements
Dietary supplements		X ¹		Proposed in 2003 ²	X		Some
Conventional foods		X ¹			X ³		Some
Food additives		X ¹	X	X	X		X
Monograph drugs ⁴	X	X		X	X		X
New Drug Application drugs ⁵	X	X	X	X	X	X	X
Infant formula ¹	X	X		Proposed in 1996 ⁶	X	X	X

Source: GAO analysis of U.S. Department of Health and Human Services, Office of Inspector General, Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve.

¹ Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub.L. No. 107-188, 116 Stat. 594, manufacturers and distributors are required to register with FDA no later than December 13, 2003.

² FDA proposed good manufacturing practices in March 2003. Comments are due to FDA by August 11, 2003. Regulations regarding the packaging of dietary supplements containing iron were issued in 1997.

³ FDA does not collect or evaluate all adverse event reports on all conventional food. In addition, excluded from this system are the investigations FDA conducts following food-borne illness outbreaks.

⁴ Monograph drugs are typically over-the-counter drugs that must adhere to specific safety standards set for each ingredient and do not undergo clinical testing.

⁵ New Drug Applications must be submitted to FDA for all prescription drugs and some over-the-counter drugs prior to marketing. This application must include data that demonstrate the safety and efficacy of the product.

⁶ The comment period for the proposed good manufacturing practices regulation was reopened in June 2003, and closes August 26, 2003.

Mr. GREENWOOD. Thank you very much, Dr. Crosse.

The Chair recognizes himself for inquiry, and I'm going to start out with the question to Dr. Woosley. I think I know the answer to this, but I would like to present it for the record.

The President of one of the ephedra companies has proposed funding a long term study of ephedra to settle some of these issues. What is your response to that?

Mr. WOOSLEY. Mr. Chairman, you are right, you do know my answer. As I said, we do not need further studies.

In the first place, this is an unethical study that would have to be done. You would have to expose people without medical supervision and without medical screening to ephedra in order to answer this question. Because that is the way it is being used by the public.

That study will never get passed an institutional review board. We sort of hold ourselves here and we ask, do you think we could go back to our institutional review board with a study proposal and get it approved to answer this question does unsupervised use of ephedra-containing alkaloids have any health benefit or risk? The answer is no, that study cannot be done. And it does not need to be done. This study has been done in the public and the deaths are documented and the testimony has been provided.

Mr. GREENWOOD. Thank you, sir.

Second question that I would like you and/or Dr. Zipes to respond to. Cytodyne Technologies has provided this committee with a report by Dr. Michael Baden to dispute the cause of Mr. Bechler's death. Mr. Baden says that there are no medical articles linking health stroke and ephedra.

And at this time I would like, without objection, enter into the record the report of the Broward County, Florida Coroner, dated July 23, 2003, which was a response to Dr. Baden's study regarding the role of the ephedra-containing food supplement in the death of Steven Bechler.

[The information referred to follows:]

MEDICAL EXAMINER AND TRAUMA SERVICES
5301 S.W. 31st Avenue, Fort Lauderdale, Florida 33312 • 954-327-8500 • FAX 954-327-8580

July 23, 2003

Honorable James C. Greenwood
Chairman Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representative
Washington, D.C. 20515-6115

Re: Role of the Ephedra-containing food supplement in the death of Steven Bechler

Dear Chairman Greenwood:

My name is Joshua A. Perper and I am the Chief Medical Examiner of Broward County, Florida. In this capacity I conducted the investigation of the unfortunate death of Mr. Steven Bexler. I performed an autopsy and determined the cause of his death as well as the risk factors leading to death and the manner of death. (Please see the attached Investigative Report)

The reason for the writing of this letter is to respond to critical allegations of Dr. Michael Baden, a forensic pathologist consultant for CytoGene Technology, who disagreed on several grounds with my determination, that ephedra alkaloids components of Xenadrine, a food additive, taken by the athlete constituted one of several significant risk factors leading to his death.

Before answering Dr. Baden's comments of which I became aware and I had the opportunity of reviewing only yesterday, July 22, 2003, I would like to summarize succinctly my determinations in Mr. Bexler's case.

Steven Bechler, a nationwide minor professional baseball player, collapsed during a training run, and died several hours later in a local hospital of a heartstroke. The autopsy findings revealed the presence of an enlarged heart, associated liver damage, a virtually empty gastrointestinal tract and extensive internal bleeding and confirmed that the cause of death was heartstroke with multi-organ failure and internal hemorrhages. Further investigation revealed that the heartstroke resulted from the convergent action of a number of risk factors including: obesity, excessive dieting in the days prior to the collapse, increased environmental temperature and humidity, physical exertion, lack of acclimatization to the Florida's warm weather, inadequate conditioning, a clinical history of hypertension and asymptomatic liver abnormalities and the intake of Xenadrine RF, a food supplement which is advertised as being effective in drug weight reduction and energy enhancement.

The reasons for determining that Ephedra containing alkaloids were a significant contributing factor to the fatal heatstrokes, included the following:

1. Mr. Beathler took the Ephedra-containing compound daily for several months in total amounts greater than according to the manufacturer's label.
2. The known physiological actions of ephedrine increase the risk of a heat stroke by:
 - a. Increasing the body's temperature. (Ephedrine is known to be a thermogenic drug and in fact the ephedrine-containing food supplement is advertised as being thermogenic i.e. a drug that raises the body temperature by "burning" more efficiently body fat.
 - b. Decreasing the sweating capability of the skin

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FROM MEDICAL EXAMINER

c. Decrease in the body's capacity of losing heat, caused by the ephedrine related constriction of blood vessels (capillaries) in the skin. It should be noted that when body temperature increases above thermo-regulatory set points, heat dissipation depends primarily on activation of sympathetic cholinergic fibers that lead to sweating and cutaneous vasodilatation - and ephedra or ephedrine are blocking both processes.

3. The presence in Mr. Bechler ante-mortem blood of significant levels of ephedrine.

Dr. Baden claims that ephedrine played no role in the death of Mr. Bechler and that in general ephedrine is not and cannot be linked to the occurrence of heatstroke.

In support of his thesis, Dr. Baden advances a number of statements or arguments, which are clearly refuted by the following facts:

1. On page 2 of his report Dr. Baden indicates that he had no "access to EMT-Fire Rescue records of February 16, the North Ridge Medical Center Hospital records of February 16, and 17, past medical records, the autopsy microscopic slides and photographs, and the interviews of the witnesses to Mr. Bechler's collapse and initial treatment" Mr. Bechler's actual clinical medical records, and the photographs of the autopsy are shielded from disclosure by the Florida's statutes, unless the evidence is released by the family, by judicial order or during civil or criminal procedures. However, the autopsy microscopic slides and the entirety of the Medical Examiner's files are by law Public Records and opened to all. In the telephonic conversation with Dr. Baden I informed him of the willingness of my office and of myself to fully disclose and deliver all public records or materials. As a matter of fact the attorneys for Cytodyne obtained all open records requested.

2. Dr. Baden noted correctly that the patient weight at the time of the autopsy was 320 pounds and that he was 6'2" in height, and therefore concluded that he was morbidly obese. However Dr. Baden omitted two important facts which were:

a. The fact that Mr. Bechler's weight three days before his demise was 250 lbs, and no individual, no matter how much would eat can gain 70 lbs of weight in three days. Furthermore, Mr. Bechler's gastrointestinal tract was empty and he eat very little if at all during the 2-3 days preceding his demise.

b. At the time of the autopsy Mr. Bechler was excessively bloated and edematous. This bloating was a result of both infusion of resuscitation fluids and his kidney failure with lack of urination. Therefore while Mr. Bechler was obese, his "morbid obesity" at autopsy was most likely, at least in significant part, a result of fluids infusions and renal shutdown. It is also possible that the weight of Mr. Bechler was registered incorrectly.

3. On page 5 of his report Dr. Baden notes that the "ephedrine level in Mr. Bechler's blood continue to rise three hours after he collapsed and while he was in the hospital" which indicates that he was in the absorption stage". Therefore Dr. Baden argued "that at the time that Mr. Bechler collapsed from heat stroke much of the ephedrine he had swallowed was still in his stomach and, therefore could not have produce any harmful physiological effects, the unabsorbed ephedrine - and the ephedrine in Mr. Bechler's vomitus - could not have caused or contributed to Mr. Bechler's death". Dr. Baden's facts are in part inaccurate and his argument faulty for the following reasons: Mr. Bechler's collapse occurred at 11:30 hours, he was brought to the hospital at 12:23 hours. The first blood sample made available to the Medical Examiner for analysis was taken at 13:05 hours, i.e. one hour and thirtyfive minutes after the collapse. The ephedrine level at that time was 141 ng/ml. The next sample taken at 14:40 i.e. 3 hours and 10 minutes from the collapse was 175 ng/ml. Therefore it is correct that at the time the second blood sample was collected the patient was still in the absorption stage. However it is not true that the blood ephedrine continued to rise afterward as claimed by Dr. Baden when he stated that after the three hours the blood continued to rise "while the patient was in the hospital", as further measurements show a continuous decline (see table 1 and diagram 1). Furthermore, the manufacturer himself states that the peak concentration occurs between 1-3 hours. Dr. Baden's argument that the patient was still in a very early absorption stage at the time of the collapse and therefore his blood level was too low to be significant, is not valid because calculations indicate that at the time of the collapse the level of ephedrine in Mr. Bechler's blood was significant. A back extrapolation was based on the fact that from 13:05 hours to 14:40 hours, i.e. over 1 hour and 35 minutes the blood level of ephedrine increased by about 34 ng/ml. Therefore, at the time of the collapse at 11:30 i.e., one hour and thirtyfive minutes before the collection of the first sample the

ephedrine level would be 34 ng/ml less than the concentration of the ephedrine at the time of the first sample, i.e., an ephedrine blood level of 106 ng/ml at the time of collapse. This is definitely a significant level. The classical textbook of Randall C. Baselt - Disposition of Toxic Drugs and Chemical in Man (6th. Edition 2002 Biochemical Publications, Foster City, CA) quotes on page 381, clearly indicate substantiates that such level is physiologically significant by citing :

- a. A study of 12 healthy adults given an oral dose of ma huang powder containing 19.4 mg ephedrine developed peak plasma concentration averaging 0.081 mg/L at 3.9 hours (i.e. 81ng/ml)
- b. A single 24 mg oral dose of ephedrine given to a volunteer resulted in a peak plasma concentration slightly exceeding 0.100 mg/L (i.e. 100 ng/ml) after 1 hour, declining to about 0.068 mg/L (68ng/ml) by 3 hours.
- c. A patient receiving chronic daily oral therapy with 45 mg of ephedrine in three divided doses achieved plasma concentrations of 0.095 mg/L (95 ng/ml) and 0.063 mg/L at 4 and 6 hours after one 15 mg dose.

4. Dr. Baden infers that I committed myself to the conclusion that ephedrine contributed to Mr. Bechler's date before toxicology and microscopic studies, inferring that such commitment was improper before "full medical information could be obtained" and only or mainly because a bottle of Xenadrine was found in Mr. Bechler's locker. Dr. Baden is again significantly inaccurate in the facts and wrong in the conclusions. Before the press conference took place the following items of information were in my possession:

- a. The gross autopsy findings
- b. Telephonic interviews with the members of the team who saw Mr. Bechler before collapse, at the time of collapse and after the collapse and with the ones who assisted him.
- c. The EMS and hospital records
- d. Mr. Bechler's medical records and examination in his medical file with the team
- e. The gross autopsy findings in conjunction with the medical history and records providing the information required for the determination of the cause, manner, and mechanism of death as well as the risk factors associated with the heatstroke.
- f. Members of the team that knew about him taking Xenadrine and the fact that a bottle of Xenadrine was in his locker and later retrieved and delivered as evidence
- g. The fact that he took Xenadrine the very day of his death and the amount taken by him
- h. The fact that we had received from the hospital multiple sequential pre-mortem blood samples, taken less than 2 hours after the collapse and on.
- i. The knowledge of the physiological effects of ephedrine. (See above)

Based on all of the above information I felt confident that the toxicological examination would show the presence of ephedrine (as indeed it did) and that there will be no microscopic surprises. It should be noted that Dr. Baden did not make any effort to obtain the microscopic slides, an easily obtained public record item. I believed that in view of the special circumstances of the case, withholding clear determinations and information that might save lives was ethically improper and that the public health interest required prompt disclosure.

5. Dr. Baden then stated that I acknowledge at a press conference that I knew of no prior instance in which ephedrine has caused a death from heat stroke, and that I stated that "no other drugs were found in Mr. Bechler's blood on admission to the hospital, despite the toxicological findings of increased DHEA, which is not present in Xenadrine." It is my recollection that I stated that I did not have a prior case in which ephedrine was a factor in the causation of death, not that such case never occurred to my knowledge. (Incidentally a further recent review of our heartstroke cases revealed another instance in which ephedrine was present.) Dr. Baden's implication that increased DHEA was another exogenous drug found in Mr. Bechler's blood is incorrect and misleading. DHEA (Dehydroepiandrosterone) is a steroid hormone, a chemical cousin of testosterone and estrogen, normally present in the blood, and the levels of the hormone were not indicative of exogenous intake. Furthermore, no information whatsoever indicated that Mr. Bechler had used at any time steroids.

6. Dr. Baden stated that during the "same press conference" I referred to the Rand report, and the Rand report found no evidence at all of ephedrine related heatstroke. I do not believe that during my initial press conference I referred to the Rand report, because it was not issued yet. At the second and final press conference I referred to the Rand Report in mentioning that the report clearly indicated that ephedrine has very little benefits and a great deal of adverse reports, including deaths, that require further extensive studies and evaluation, and that the risks do not outweigh the benefits.

7. Dr. Baden then stated that a review of the medical literature, revealed "not a single case report linking ephedra or ephedrine to heat stroke", and that no such case was ever reported. Dr. Baden also states that I relied on Dr. Julius Bailes' report published in the Journal of Neurosurgery in 2002 as "one of a particular importance in reaching the conclusion that ephedrine was a significant factor in causing Mr. Bechler's case". Dr. Baden denies any validity to Dr. Bailes' conclusions, stating that none of the reported death was related to ephedra. He states "Correlation is not causation", and that a Medical Examiner cannot rely on such study in his determination of cause of death and that a number of letters to the Editor strongly disagreed with Dr. Bailes' opinion. Dr. Baden's statements are largely incorrect and misleading for the following reasons:

At no time did I say that Dr. Bailes' study played an important role in my determination of the cause of death of Mr. Bechler. As a matter of fact I did not consider his article at all at the time when I made my determination of the cause of death of Mr. Bechler. Dr. Bailes sent me a letter dated February 25, 2003, and attached to it his article in the Neurosurgery Journal of which I was not aware. Furthermore while per se "correlation is not causation" when the correlation is substantial and is reinforced by known and well documented patho-physiological effects such as is the case with ephedra or ephedrine, the inference of causation is reasonable. It is true that Medical Examiners do not make specific determination of the cause of death based on epidemiological or statistical medical studies, the opposite is true. However, epidemiological studies are helpful in the decision making process of every physician, including medical examiners, and assists them in their consideration of the specific features and circumstances of the medical issues.

8. Dr. Baden's statements that the medical literature is void of case reports or studies correlating ephedra or ephedrine with the risk of developing heat stroke is plainly wrong as demonstrated by reports published both before and after the death of Mr. Bechler:

a. The publication:

i. CPT Robert Chu Hwan, CPT Jeffrey Scott Henning Exertional Heatstroke in an Infantry Soldier taking Ephedra-Containing Dietary Supplements Military Medicine 168 (6): 429 - 430 June 2003 Case report of a highly trained, heat acclimatized infantry soldier who experienced an exertional heat stroke during a 12-mile road march shortly after taking an ephedra-based supplement. The ambient temperature at the time was 66°F. The patient's core body temperature at the time of collapse was 106°F. The patient fortunately survived and was discharged after 5 days of hospitalization. The article ended in stating: "Until the Food and Drug Administration makes a decision to remove ephedra from the U.S. market, the risk of life threatening injury may outweigh any real or perceived benefit of ephedra and clinicians and commanders should strongly discourage its use in active duty soldiers."

b. The publication:

i. M. Martinez Drug- Associated Heat Stroke South Med. J. 95(8): 799-803 2002 The report indicates that drugs with sympathomimetic action include "cocaine, amphetamine, and ephedrine/pseudoephedrine, which are present in over-the-counter decongestants and popular dietary agents (ma huang). The report adds that "sympathomimetics elevate body temperature by two main mechanisms. First, cutaneous blood flow is decreased by vasoconstriction, reducing heat loss. Second heat production is increased by expanded muscular activity from agitation and seizure activity."

c. The publication:

- i. Richard P. Sandor Heat Illness On-Site Diagnosis and Cooling
 The Physician and Sports Medicine 25(6) June 1997 The report reviews the mechanism,
 risk factors, diagnosis and treatment of heatstroke. It indicates that the risk factors for heatstroke include:
1. Increased endogenous heat load
 - a. Overexertion
 - b. Drugs (e.g. sympathicomimetics, caffeine)
 2. Increased exogenous heat load
 - a. Temperature
 3. Amongst drugs that predispose to heatstroke, sympathicomimetics are the first category listed and include
 - a. Amphetamines
 - b. Epinephrine
 - c. Ephedrine
 - d. Cocaine

- d. The publication:
 Bailes J.E., Cantu RC, Day AL. The Neurosurgeon in Sport: Awareness of the
 Risks of Heatstroke and Dietary Supplements Neurosurgery 51(2): 283-288,
 2003 The editorial discusses the study review of authors who found that there was a total of 6 heat stroke deaths
 among US athletes between 1985 and 1994, but there were four death per year in 1995, 1998, 2000 and 2001.
 In a letter addressed to the underwriter and dated February 25, 2003, Dr. Jules E. Bailes Jr., a Professor and
 Chairman of the Department of Neurosurgery, states regarding his study that in reporting the association of
 heatstroke deaths in athletes with recent changes in athletes behavior the authors "felt very strongly that
 amphetamines compounds such as ephedrine were the most likely culprit in this upward trend."

- e. Report of adverse reactions to ephedrine-containing food supplements:
 i. Released by U.S. Department of Health and Human Services # 9754 on April 22, 1997
 A 44 year-old woman was known to be on the product when she developed heat stroke, chest and back pain,
 hyperthermia and tachycardia while exercising.

- f. Case law: Gehling v. St. George's University School of
 Medicine, Ltd 705 F.Supp 761 (E.D.N.Y. 1989) Plaintiff Rose Ehling brought this negligence action after her son Earl, a
 medical student, collapsed and died of a heat stroke while participating in a "road race" sponsored by the defendant. On
 April 18, 1982, Earl Gehling ran in a race approximately 2.5 miles, The race took place in a left afternoon when the
 temperature was hot about 80-85 degrees Fahrenheit and the humidity was high. Gehling was 25 year old, stood 5'10"
 and was about 75 pounds overweight. He suffered from high blood pressure and his left ventricle was enlarged
 (hypertrophic). Gehling had taken ephedrine, an "amphetamine like drug" before the race". The race started at 4 pm and
 ended at 5 pm. After he crossed the line he collapsed, struggled up and then fell again.
 He became "hysterical" and had to be restrained. His temperature remained high in spite treatment at the scene, was
 transported to the hospital and died about 7 hours after admission,

- g. Experimental studies in animals have shown marked hyperthermia in addition to other toxic effects of ephedrine, for
 example: - Records of dogs that had ingested an herbal supplement containing ma huang and guraana between July 1997
 and October 1999 were retrieved from the National Animal Poison Control Center database. Most dogs (80%) developed
 thyrotoxicosis but 28% developed hyperthermia.
 Experimental studies on mice also demonstrated the ephedra capability to cause hyperthermia.

- h. In spite of Dr. Baden's claim of total lack of documentation or data about the correlation between ephedra or
 ephedrine and heat strokes not just non-medical sport organization but professional health care or medical association

such as the American Medical Association issued warnings about the capability of ephedra or ephedrine to trigger, or increase the risk of exertional heat stroke. For example:

i. The American Society for Pharmacology and Experimental Therapeutics (ASPET) in a Statement on the Use of Dietary Supplements and Ephedrine, issued in June 2003, after supporting "regulations and legislation to amend the Federal Food, Drug, and Cosmetic Act that would establish requirements, and restrictions of sales of dietary supplements containing ephedrine and pharmacologically related stimulants" also noted: ASPET believes that dietary supplements containing ephedrine alkaloids present a clear, significant, and unreasonable risk of illness, injury or death under conditions of use (currently) recommended or suggested in the labeling of ephedrine products * The statement also specifies: "Potentially significant adverse events included death from increase in heart rate and blood pressure, stroke, acute psychoses, and heart attacks. Insomnia, heat stroke and increase urinary retention associated with the use of ephedrine in both minors and adults have also been reported."

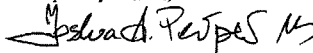
ii. The New York State Office of Alcoholism and Substance Abuse Service issued on April 1, 2003, a warning entitled EPHEDETRA, regarding the risk of taking over the counter ephedrine-containing products. The EPHEDETRA paper released clearly states: "Adverse effects of ephedrine include: death, heart attacks, strokes, seizures, dizziness, headache, nausea, vomiting irregular heart beat and palpitations, restlessness, insomnia, psychosis, memory loss and muscle injury. Serious thermogenic effects, such as heat stroke, are caused by ephedrine's ability to increase body temperature; this effect is intensified by caffeine. Ephedrine should never be used by someone with hypertension, diabetes, thyroid disease or an enlarged prostate taking antidepressant medications or breast feeding. Adverse effects do not always depend on the dose consumed."

In conclusion, after reviewing the critical remarks of Dr. Michael Baden, I found them to lack substance and sound medical reasoning, in ignoring the well known thermogenic patho-physiological effects of ephedra and ephedrine which clearly increase the risk of heatstroke. The heatstroke related risk of ephedrine and ephedra consumption are well supported by medical evidence, and acknowledged by health care and medical bodies.

Furthermore it should be emphasized that heat stroke occurrence is only one of the many adverse events reported following the use of ephedra or ephedrine-containing over the counter medications.

I thank the Chairman and the Committee very much for making the letter of Dr. Baden available to me, so that I could prepare a timely response.

Respectfully submitted,



Joshua A. Perper, M.D., LL.B., M.Sc.
Chief Medical Examiner

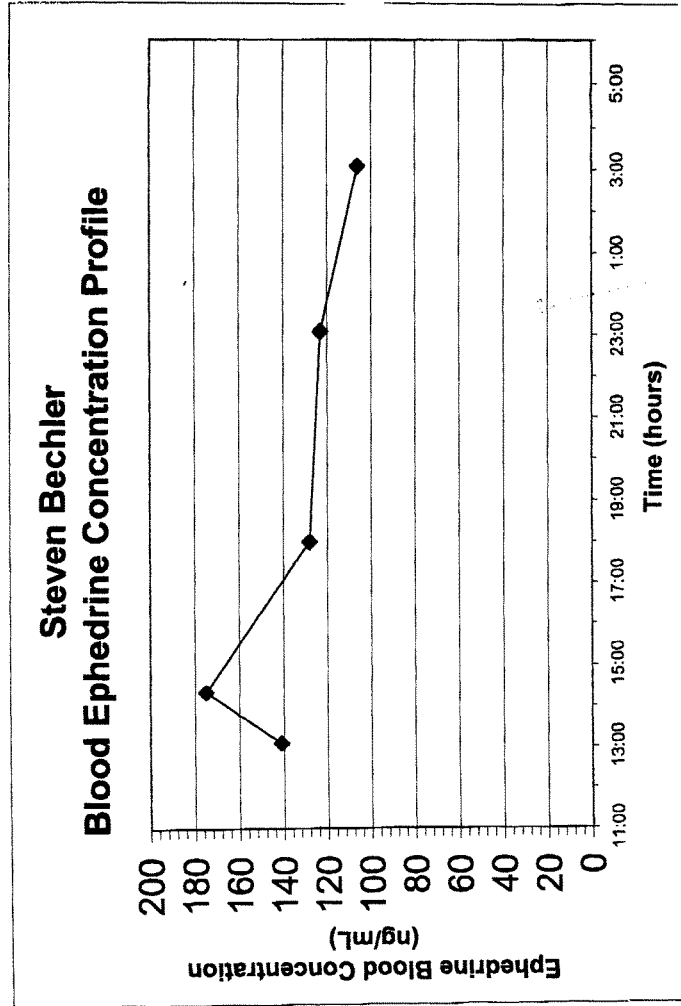


Diagram 1

Bechler, Steven

BME2003-0245

Blood Levels of Ephedrine

Antemortem:

Date/Time	Specimen	Ephedrine Level	Note
02/16/03 1305	Blood	141ng/mL <50ng/mL pseudoephedrine	200ng/mL found by NMS*
02/16/03 1420	Blood	175ng/mL <50ng/mL pseudoephedrine	
02/16/03 1800	Blood	128ng/mL <50ng/mL pseudoephedrine	
02/16/03 2306	Blood	123ng/mL <50ng/mL pseudoephedrine	
02/17/03 0306	Plasma	106ng/mL <50ng/mL pseudoephedrine	

Postmortem:

Specimen	Ephedrine Level	Note
Heart Blood	200ng/mL <50ng/mL pseudoephedrine	270ng/mL found by NMS*
Ocular	229ng/mL <50ng/mL pseudoephedrine	
Liver	0.45mg/kg <0.25mg/kg pseudoephedrine	
Bile	~ 1563ng/mL <50ng/mL pseudoephedrine	

Additional Toxicological Findings:

Antemortem blood (02/16/03 1305) positive for diltiazem.

Postmortem blood positive for diltiazem, meperidine, diazepam and atropine.

Ocular positive for meperidine.

Liver positive for diltiazem, meperidine and diazepam.

Bile positive for diltiazem and meperidine.

*NMS = National Medical Services, Inc.

Table 1

(WED) 7:25:03 8:18/ST. 8:16/NO.4863127050 P 9

FROM MEDICAL EXAMINER

Mr. GREENWOOD. Would you respond to Mr. Baden's statement?

Mr. WOOSLEY. Yes, Mr. Chairman.

There are numerous reports of ephedra inducing heatstroke. There are animal studies documenting the ability of these compounds to cause excessive temperature in animals. This is a known pharmacologic effect of this entire class of compounds.

Drugs like ephedrine that cause your blood vessels to constrict prevent your body from releasing heat, and especially during exercise but it does not always require exercise. The body temperature can reach levels that cause stroke, cause death. It is well documented in the medical literature.

Mr. GREENWOOD. Dr. Zipes, do you want to add to that?

Mr. ZIPES. Mr. Chairman, I would certainly agree with what Dr. Woosley has said.

I think it is very important to recognize that we are different people. There is biologic pleomorphism, we are not all the same. We do not respond all the same to the same drug. We now know, as an example, that there are generic influences of this "fight" or "flight" type reaction that I spoke about. There are individuals who have an excessive response with an excessive release of adrenaline and do not take it back up into the nerves so that it is floating in the body and can cause a lot of the problems that we are talking about.

So that there would be no way to do a prospective trial and screen for all of these individuals who may represent the bulk of the adverse responses that we are seeing. And it is because of this heterogeneity that exists that there may be 1 in a 1,000 or more that would have an adverse response.

Mr. GREENWOOD. And it seems to me as I have pondered this issue for the last several months that the real line of demarcation should not be whether the product is made from a plant that comes from somewhere in the world or not, but it is the extent of the physiological response that it engenders in human beings that is the real question, and particularly the extent of the potentially life threatening physiological response. And that seems to me to be our duty to take under consideration.

Let me turn to Mr. Vasquez. Can you hear me still, Mr. Vasquez?

Mr. VASQUEZ. Yes, sir.

Mr. GREENWOOD. Thank you for remaining and for your patience.

When you worked at Metabolife did you hear your coworkers voice any concerns about the safety of the company's products?

Mr. VASQUEZ. Yes, sir. We had discussions in the lunchroom in regards to, you know, the calls that we took. As nurses we would compare notes, like I said earlier. And basically, you know, ask questions about whether—is this product really safe or why we get so many calls. And you have to wonder, I mean, if people are taking the product and they see an 800 number on the bottle, they call it. And they would ask why am I feeling like this, whatever symptoms they are complaining about or calling for. Is this normal, they would ask.

And it was basically a health concern from a medical perspective.

Mr. GREENWOOD. Do you know if one of your coworkers whom you had heard voice such concerns was fired for doing that?

Mr. VASQUEZ. When I was no longer employed in the company I inquired about this specific nurse and they said that she was let go because she was very vocal about the product, whether you know, it was doing more harm than good.

Mr. GREENWOOD. Were you warned or persuaded by your supervisor at Metabolife not direct complainants to describe their symptoms but instead to just take their name and phone number and give that to your supervisor?

Mr. VASQUEZ. It would depend on the severity of the call. Some if it is minor like abdominal cramps, then you know you would document that. We documented all calls. But if it was moderate to severe, you had a procedure where we would take as much information as we can get without being judgmental and I would forward it to my supervisor Mr. Daniel Rodriguez. And we were basically left in the dark and we would not know what happened to that specific case. Mr. Rodriguez was the one who was basically the key person that would follow up on specific case.

Mr. GREENWOOD. Did anyone at Metabolife including your supervisor at the Health Information Line, Mr. Rodriguez, monitor your responses to customers who were complaining of adverse events or negative side effects as a result of taking Metabolife?

Mr. VASQUEZ. Like I said earlier, there were 10 registered nurses on staff and Mr. Rodriguez and the medical director, Dr. Smith, had the ability to listen to all the calls that were coming in. And if they heard something, specifically Dan Rodriguez, heard something that one of the nurses would say, right after the call he would critique, for example, myself and say probably you should have answered that call that way.

Mr. GREENWOOD. Did you feel under any pressure to conduct yourself in those phone calls in any way other than you would given what you said earlier in your testimony that you wanted to just do no harm?

Mr. VASQUEZ. At times, yes. Because as a nurse it seemed like the telemarketer script the kind of answer you would give out and, you know, I was trained as a nurse, I went to school, nursing school. You know, basically you had to really be more impersonal than you cared.

While I was working there there was no nurse/patient/consumer relationship that would, you know, you would be looking out for the best interest of the caller rather than the—

Mr. GREENWOOD. Did you feel that you were functioning more as a marketer of the drug than as an advocate for the patient?

Mr. VASQUEZ. Definitely I wouldn't say marketer, because they had a lot of advertisement. So not as a marketer. But more like, you know, less of an advocate from a medical professional, I would say so.

Mr. GREENWOOD. Thank you, sir. My time has expired.

The gentlelady from Colorado is recognized for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

My first question is for the Bechlers and for Mr. Riggins, because there are a lot of dietary supplements being sold now in the stores and, you know, all my middle aged friends and I sit around and talk about what we should be taking to make ourselves feel better. And listening to all the testimony today, it kind of makes me real-

ize people probably think that these products are safe because they are not prescription drugs or a doctor's order is not required. Do you think that that's probably true, Mrs. Bechler?

Ms. BECHLER. I do. In fact, my son as I hear it from his wife—

Ms. DEGETTE. Just move that a little closer. That helps. Yes.

Ms. BECHLER. As I hear it from his wife, she got it at workout place that she worked out at. And so you—

Ms. DEGETTE. So they were giving it out at the gym?

Ms. BECHLER. Yes. In fact, my other son and I worked out at a gym and they have it there. So why would not you natural think that it is going to be as natural and it is herbal, and it is safe.

Ms. DEGETTE. And, Mr. Riggins, what is your view on that?

Mr. RIGGINS. In our discussions with kids, and when I say kids I am not just talking about high school students. We are talking about college athletes as well, college students that are looking to lose weight and with the general public. We have found that when you start bringing the awareness out, when you tell them that the FDA does not have—only has minimal control over these companies, the majority of the people are appalled at that. They just cannot understand how come a law will allow a company just to run, as one individual put it, helter skelter.

Ms. DEGETTE. But up until they know that information, they just assume that the product is safe because it is being allowed to just be sold helter skelter to the consumers, would you not agree?

Mr. RIGGINS. That is exactly right. Exactly right.

Ms. DEGETTE. Thank you.

Dr. Heymsfield, I was intrigued by your testimony where you were talking about the product labeling and you were talking about when you began doing your research there was no product labeling as to the dangers, and in fact some of the labels said clinical tested. Is that correct?

Mr. HEYMSFIELD. Well, some of the bottles had statements, for example, "independently laboratory tested for safety."

Ms. DEGETTE. Have you looked at bottle of Metabolife recently?

Mr. HEYMSFIELD. I have not looked at a recent bottle, no.

Ms. DEGETTE. Okay. I have got one here in my hands.

Mr. HEYMSFIELD. Yes.

Ms. DEGETTE. And there this big warning on the side of the label here. Are you familiar with that warning?

Mr. HEYMSFIELD. Yes. Yes.

Ms. DEGETTE. Do you know when they started putting that warning on these bottles?

Mr. HEYMSFIELD. I am not aware of the date of when that appeared.

Ms. DEGETTE. Does anyone else know roughly when this warning started appearing?

Mr. FRANCE. Jim France here, attorney for the Bechlers. I believe it was early 2001.

Mr. GREENWOOD. Excuse me. I have to quickly swear you in if you are going to actually speak.

[Witness sworn.]

Mr. GREENWOOD. Okay. You are under oath now.

Ms. DEGETTE. Mr. France, proceed.

Mr. FRANCE. Yes. In 1999 they were using another label that had “independently laboratory tested for safety” where that silver decal is on the front.

Ms. DEGETTE. This right here?

Mr. FRANCE. Yes. And then there was a class action lawsuit called Gasperoni v. Metabolife that occurred in the year 2000. And as a part of that settlement it is my understanding that they could not advertise that their product was independently laboratory tested for safety anymore and they put that little decal on the front. And then they started selling the product—

Ms. DEGETTE. It is a butterfly.

Mr. FRANCE. Yes. It is a silver decal—

Ms. DEGETTE. It is a butterfly.

Mr. FRANCE. It is a butterfly. They put the butterfly over the safety claim in 2001, I believe.

Ms. DEGETTE. And that is when they put the safety warnings on?

Mr. FRANCE. And they added additional safety warning information, but they failed to include the fact that they had received thousands of AERs.

Ms. DEGETTE. Okay. Thank you.

Going back to Dr. Heymsfield. Thank you for helping us, sir.

You said that the studies were flawed that were done by the companies. I am wondering if you can tell me quickly some of the reasons why you feel those studies were flawed?

Mr. HEYMSFIELD. Well, this is my opinion, but some of the published papers, for example, would report that effects were statistically significant. And that has very specific meaning to a scientist. But actually when you investigate the raw data in the actual statistics, they did not achieve specific significance. That was never revealed in the papers. They were misrepresented. And I could give you many examples like that of where—

Ms. DEGETTE. And I think in addition, Dr. Woosley and others said that the studies were not scientifically controlled because IRB would ever approve that kind of a study?

Mr. HEYMSFIELD. Well, no longer. I mean, at the time the adverse events were not as clearly recognized. But I today I agree with them.

Ms. DEGETTE. Okay. Thank you.

Mr. GREENWOOD. The time of the gentlelady has expired. The gentleman from New Hampshire is recognized to inquire for 5 minutes.

Mr. BASS. Thank you, Mr. Chairman. I have one question. Do any of the doctors here see any medicinal value to ephedra? Is there any reason—Okay. That is the only question I have.

I will yield the rest of my time to my friend Mr. Walden.

Mr. WALDEN. Thank you very much.

I would like to address my first question to the Bechlers, and I know this is a difficult one, but how did you feel when the Broward County Coroner concluded that ephedra was “a significant factor” in your son’s death?

Mr. BECHLER. When they told us about it, we knew it had to be something. It just was not heatstroke because he was in perfect condition. I mean, there was nothing wrong with our son. Nothing.

Mr. WALDEN. There have been reports that I have read in the press that said he was terribly overweight. How overweight was he went he went into camp?

Ms. BECHLER. Ten pounds.

Mr. BECHLER. Ten pounds.

Mr. WALDEN. Ten pounds?

Mr. BECHLER. His body fat was less than it was a year before.

Ms. BECHLER. Which the Orioles was impressed about.

Mr. WALDEN. You need to turn on your mike.

Ms. BECHLER. Which the Orioles were impressed about with just the 10 pounds, but his body fat had gone down.

Mr. WALDEN. Okay. And I guess I want to ask Mr. France this question, because I was reading the testimony last night of the President of Nutraquest, Inc., former Xenadrine Technologies, Mr. Chinery, is that right? And in it he says we sold over 20 million bottles of Xenadrine RFA-1, which is what I think what your son took. About 1.2 billion servings. And I understand the comment of our other witness on that. And received 450 complaints during the 5 years we sold the product. The great majority of our complaints were from mild or transitory effects. Based on all the available scientific information we did not have any reason to believe that Xenadrine RFA-1 caused anything but mild transitory effects. We relied upon studies not only on Xenadrine RFA-1 but also on studies on other ephedra dietary supplements and on Xenadrine's principle ingredients, ephedra and caffeine.

Studies including the Cantox Report show that ephedra based products are effective and safe when used properly.

Mr. France, first of all, are you familiar with any studies that would confirm that? Would what I have reasoned indicate to the contrary?

And second, are you aware of any court documents relating to how others have perceived the credibility of these witnesses?

Mr. FRANCE. Yes, I am. First of all, there was a trial against Xenadrine in which Mr. Chinery testified about a month and a half ago. And during that trial several of the alleged clinical studies that took place on Xenadrine RFA-1 were discussed by expert witnesses on both sides. And to reiterate what Dr. Hymnsfield said, there was manipulation of research data found and disclosed during that trial. The trial judge found there were significant problems with several of the studies that Xenadrine was holding to prove efficacy and/or safety.

And more importantly, the trial judge found in its verdict, a written verdict, that Mr. Chinery, Mr. Conklin, who is here today, Dr. Colker had no credibility. And the judge sat through almost 7 weeks—

Mr. WALDEN. The judge said that?

Mr. FRANCE. The judge said that in a written opinion. And I have it here today.

Mr. WALDEN. Mr. Chairman, would it be possible to have that written opinion entered into the record?

Mr. GREENWOOD. Without objection, it will be incorporated into the record.

[The information referred to follows:]

Slip Copy
(Cite as: 2003 WL 21283814 (Cal.Superior))

Page 1

Only the Westlaw citation is currently available.

California Superior Court, County.

**Jason A. PARK, on behalf of himself and all
others similarly situated,
Plaintiff,**

v.

**CYTODYNE TECHNOLOGIES, INC., a New
Jersey corporation; and Does 1 through 100,
inclusive, Defendants.**

No. GIC 768364.

May 30, 2003.

TENTATIVE DECISION

STYN, J.

INTRODUCTION

*1 Plaintiff Jason A. Park, on behalf of himself and all others similarly situated, filed a complaint against defendant Cytodyne Technologies, Inc., a New Jersey corporation. The complaint was certified as a class action.

Cytodyne markets and sells Xenadrine RFA-1, a dietary supplement commonly used as an aid in weight loss. The active ingredients in Xenadrine RFA-1 include ephedra and caffeine. Cytodyne advertises Xenadrine RFA-1 through magazine, television, and radio advertisements.

PLAINTIFF'S CAUSES OF ACTION

Plaintiff's complaint alleges three causes of action. The first claim alleges violations of the Consumer Legal Remedies Act ("CLRA"), California Civil Code sections 1750 et seq. Plaintiff's CLRA allegations couch plaintiff's false advertising allegations in the context of a CLRA claim. There is very little relevant case law addressing alleged violations of the CLRA. One court has considered claims of false advertising alleged to violate the CLRA as well as Business and Professions Code sections 17200 and 17500 et seq. and held that statements found to be not false or misleading under sections 17200 and 17500 et seq. are also not false representations under the CLRA. *Freeman v. Time, Inc.*, 68 F.3d 285, 290 (9th Cir.1995). Thus, the relevant legal standard and the burden of proof are set

forth below in the discussion of plaintiff's claims under Business and Professions Code sections 17200 and 17500 et seq.

Plaintiff's second cause of action alleges false and misleading advertisements in violation of Business and Professions Code sections 17200 et seq. The third cause of action alleges false and misleading advertisements in violation of Business and Professions Code sections 17500 et seq. Plaintiff's factual allegations in these two causes of action are identical. Plaintiff does not allege any violations of sections 17200 et seq. other than the alleged false and misleading advertising that would also violate sections 17500 et seq. Further, cases addressing false advertising claims under both statutes have applied the same legal standard to both. See *Day v. AT & T Corp.* (1998) 63 Cal.App.4th 325. For these reasons, the causes of action under sections 17200 et seq. and sections 17500 et seq. will be discussed together.

BURDEN OF PROOF

1. Plaintiff Must Prove Statements Were False or Misleading and Made Without Reasonable Care.

Sections 17500 et seq. prohibit negligent or intentional dissemination of false or misleading advertising. *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.* (2003) ____ Cal.App. 4th ____; 133 Cal.Rptr.2d 207.

Specifically, these statutes proscribe the making or dissemination before the public in California of any statement concerning the product that "is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof.Code § 17500.

Thus, to maintain a claim of false or misleading advertising, a plaintiff must prove: (1) statements in the advertising are untrue or misleading, and (2) defendants knew, or by the exercise of reasonable care should have known, that the statements were untrue or misleading. *People v. Lynam*, (1967) 253 Cal.App.2d 959, 965.

*2 The plaintiff must carry both the burden of producing evidence and the burden of proving that each challenged advertising claim is false or misleading. *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, *supra*, citing

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(Cite as: 2003 WL 21283814, *2 (Cal.Superior))

Page 2

South Bay Chevrolet v. General Motors Acceptance Corp. (1999) 72 Cal.App. 4th 861, 878).

2. Plaintiff Must Prove Public Is "Likely To Be Deceived."

A plaintiff must prove that the public is "likely to be deceived" by the statements at issue in an advertisement.

"Likely to deceive" implies more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the phrase indicates that the ad is such that it is probable that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.

Lavie v. Proctor & Gamble Co. (2003) 105 Cal.App. 4th 496, 508.

3. Advertisers Are Not Required to Produce Substantiation for their Advertising Claims.

Advertisers are not required to produce substantiation for their advertising claims in actions brought by private plaintiffs under Business and Professions Code sections 17200 et seq. and 17500 et seq. In *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, *supra*, the plaintiff argued that private plaintiffs are in the same position as the Attorney General and that the court should thus shift the burden of production and require advertisers to produce evidence substantiating the truth of their advertising claims. The Court of Appeal rejected that argument. The court held that private plaintiffs have the burden of producing evidence to prove their allegations that challenged advertising is false or misleading.

4. Statements Must Be Material To Be Actionable.

In order for an alleged false or misleading representation to be actionable, the statement at issue must be, among other things, material. Materiality is part of the "reasonable consumer" standard applied under the California unfair competition and false advertising statutes, in that reasonable consumers are not deceived by immaterial claims. A general discussion of the "reasonable consumer" standard, with citations to numerous relevant cases, is found in *Lavie v. Proctor & Gamble Co.*, 105 Cal.App. 4th 496, 504-512 (2003).

5. Nature of the Proof.

The law in this area was summarized in *Day v. AT & T Corp.* (1998) 63 Cal.App.4th 325, 331-32:

Sections 17200 and 17500 are consumer protection statutes designed, in part, to protect the public by prohibiting false, unfair, misleading or deceptive advertising. (*Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 211 [197 Cal.Rptr. 783, 673 P.2d 660] (*Committee*).) "To state a cause of action under these statutes for injunctive relief, it is necessary only to show that 'members of the public are likely to be deceived.' [Citations.]" (*Ibid.*) Actual deception or confusion caused by misleading statements is not required. (*People v. Dollar Rent-A- Car Systems, Inc.* (1989) 211 Cal.App.3d 119, 129 [259 Cal.Rptr. 191].) An "unfair" practice under section 17200 is one "whose harm to the victim outweighs its benefits." (*Saunders v. Superior Court* (1994) 27 Cal.App. 4th 832, 839 [33 Cal.Rptr.2d 438] (*Saunders*).) In a similar vein, the term "fraudulent" as used in the section "does not refer to the common law tort of fraud but only requires a showing members of the public "are likely to be deceived." ' [Citation.]" (*Ibid.*) No proof of direct harm from a defendant's unfair business practice need be shown, such that "[a]llegations of actual deception, reasonable reliance, and damage are unnecessary." (*Committee, supra*, at p. 211.) Section 17200 has been interpreted broadly to bar all ongoing wrongful business activity, including misleading advertising, in whatever context it presents itself. (*People v. Dollar Rent-A-Car Systems, Inc.*, *supra*, 211 Cal.App.3d at p.129.)

*3 Thus, the statutes are meant to protect the public from a wide spectrum of improper conduct in advertising. They may be invoked where the advertising complained of is not actually false, but thought likely to mislead or deceive, or is in fact false. By their breadth, the statutes encompass not only those advertisements which have deceived or misled *because* they are untrue, but also those which may be accurate on some level, but will nonetheless tend to mislead or deceive. We reiterate the point made in *Saunders*, that the concept encompassed in the phrase "likely to be deceived" has no relationship to the concept of common law fraud, which is also sometimes referred to as deception. A fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied

upon by a victim who incurs damages. None of these elements are required to state a claim for injunctive relief under section 17200 or 17500. A perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under these sections.

6. What Type of Evidence is Required to Establish the Advertisements Are Misleading.

Defendants argue that claims brought under Business and Professions Code sections 17200 and 17500 and the Consumer Legal Remedies Act, Civil Code section 1750, require plaintiff to demonstrate through consumer survey evidence that each challenged advertising claim did in fact mislead consumers.

Case law is clear that the proper standard to determine whether a claim is misleading is the "reasonable consumer test." *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App. 4th 496; *Bank of the West v. Superior Court* (1992) 2 Cal.4th 1254, 1267. The *Lavie* court rejected a broader "least sophisticated consumer" test proposed by the Attorney General. In so holding, the court did not specifically indicate what evidence was required in order to establish that an advertisement was misleading under the "reasonable consumer test." The issue framed for review was whether the trial court had "employed the wrong methodology in determining what messages were conveyed by the commercial, relying upon its own intuition rather than viewing the ads from the vantage point of a reasonable consumer." In upholding the trial court's conclusion that the commercials for Aleve were not likely to mislead, the Court of Appeal seemingly approved the trial court's intuition. *Lavie* is not dispositive as to what type of evidence is necessary to show that an advertisement was misleading because the portion of the opinion discussing the particular evidence before the trial court was not certified for publication.

Defendant relies on federal court opinions that require "consumer survey" evidence. In *Johnson & Johnson - Merck Consumer Pharmaceuticals Co. v. SmithKline Beecham Corp.* (2nd Cir.1992) 960 F.2d 294, the Second Circuit held that where a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged advertisements tend to mislead or confuse consumers. "It is not for

the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive." Rather, the Court held that the question is: "What does the person to whom the advertisement is addressed find to be the message?" According to the Second Circuit, the success of a plaintiff's implied falsity claim *usually* turns on the persuasiveness of a consumer survey.

*4 In *Haskell v. Time, Inc.* (E.D.Cal.1997) 965 F.Supp. 1398, the Court held that anecdotal evidence alone is insufficient to prove that the public is likely to be misled. Relying on *Johnson & Johnson*, the Court held that to prevail, plaintiff must demonstrate by extrinsic evidence, such as consumer survey evidence, that the challenged statements tend to mislead consumers. In *Haskell*, plaintiff presented evidence of "deception" regarding a sweepstakes in the form of declarations of a few sweepstakes customers and the declaration of one professor of rhetoric. After reviewing the alleged sweepstake statement and finding that plaintiff's interpretation was patently unreasonable, the court held the testimony of only a few customers and the expert was insufficient. The court reasoned that plaintiff needed consumer survey evidence indicating that a significant portion of the population has been misled by defendants' bulletins. "Indeed, plaintiff does not dispute that a majority of recipients neither respond to defendants bulletins nor purchase any of defendants' products. Plaintiff has therefore failed to prove that defendant's statements mislead the reasonable consumer." *Id.* at 1408.

Neither of these cases *require* the use of consumer surveys, nor have defendants cited a case with that proposition. *Johnson & Johnson* held that consumer surveys are a "usual" means of showing consumer deception. *Haskell* only held that "extrinsic evidence" was required.

The recent case, *Brockey v. Moore* (2003) 107 Cal.App. 4th 86, specifically disapproved of the methodology in *Haskell* and *Johnson & Johnson*. Like *Haskell*, the court in *Brockey* had "anecdotal evidence" of deception in the form of testimony from plaintiffs who were deceived. However, *Brockey* distinguished *Haskell* and other federal cases on the grounds that those cases involve "a very few persons claiming to be misled and do not hold that 'anecdotal' evidence can never suffice." The court in *Brockey* found no California case required a consumer survey to establish an advertisement was misleading.

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The court reasoned that the primary evidence in a false advertising case is the advertising itself. *Brockey* analogized the state unlawful advertising claims to federal cases involving the Federal Trade Commission's regulation of deceptive advertising. "The United States Supreme Court has rejected a claim that survey evidence was required ... [in] regulation of deceptive advertising," citing *Federal Trade Com. v. Colgate-Palmolive Co.* (1965) 380 U.S. 374, 391-392 [13 L.Ed.2d 904, 918, 85 S.Ct. 1035] and *Resort Car Rental System, Inc. v. Federal Trade Com.* (9th Cir.1975) 518 F.2d 962, 964. The court in *Resort Car* held there was no need to consider objections to consumer testimony because it "merely supported the inferences which can logically be drawn by scrutinizing the advertising alone."

The *Brockey* court also found an analogy with trade name disputes and cases construing California's prior unfair competition law (former Civil Code section 3369). In those cases, the courts acknowledged the "likelihood of confusion" between names was a factual question and "the comparison of the two names themselves may be adequate to establish the likelihood of confusion." Citing *Ball v. American Trial Lawyers Assn.* (1971) 14 Cal.App.3d 289, 309; *Hair v. McGuire* (1961) 188 Cal.App.2d 348, 353.

*5 Determining reasonableness is something the trier of fact--in this case, the judge--does in all types of cases. As indicated in *Brockey*, if "a person of ordinary intelligence could reasonably be deceived or confused, that is all that is required." The judge should not have to exclude himself or herself as a person of ordinary intelligence and a reasonable consumer.

Further, requiring consumer-survey-type evidence would seemingly contradict opinions which hold that proof of direct harm from a defendant's unfair business practice is not necessary for recovery. "The court may also order restitution without individualized proof of deception, reliance, and injury." *Committee on Children's Television v. General Foods Corp.* (1983) 35 Cal.3d 197, 211; *Day v. AT & T Corp.* (1998) 63 Cal.App. 4th 325, 332.

Based on the above, to establish that advertising is misleading under a reasonable consumer test should not require the use of consumer surveys. Considering that the advertisement speaks for itself, the judge is in a position to determine whether it is misleading, i.e. likely to deceive, under a "reasonable consumer"

standard.

Therefore, this Court will analyze the advertisements and apply the reasonable consumer test. If the Court finds a claim to be misleading, it means members of the public are likely to be deceived, *People v. Dollar Rent-A-Car Systems, Inc.*, 211 Cal.App.3d 119, 129 (1989), that the claim is material, in that it is likely to influence the purchasing decision, *Borden Inc. v. Kraft Inc.* (N.D.Ill.1989) 224 U.S.P.Q. 811, 819, and the defendant knew or should have known, Bus. & Prof.Code § 17500. Before addressing the specific advertisements, the Court will discuss some of the areas of contention which bear on the specific claims in the advertisements.

THE PEAK WELLNESS STUDY

In May of 1999, defendant retained Peak Wellness Inc. to conduct a study on the effectiveness of Xenadrine RFA-1. Prior to this time, there had been no clinical tests of the Xenadrine RFA-1 product, and all of the studies in the advertisements referred to generic studies, i.e., studies of either ephedrine or ephedrine in combination with other compounds such as caffeine, aspirin or L-tyrosine.

The Peak Wellness study was conducted primarily by Douglas Kalman under the supervision of Dr. Carlton Colker. The study began with 30 overweight subjects. Sixteen were in the control group and 14 were in the placebo group. This was a double blind study.

By the end of the study, four in the control group had dropped out and one in the placebo group, leaving a total of 25 subjects who completed the test: 12 in the control group and 13 in the placebo group.

Dr. Qiuhi Shi did a biostatistical analysis of the results. The use of Dr. Shi's information and the results of the study were the subject of a great deal of testimony during the trial.

An abstract of the study, summarizing the results, was published in the *Obesity Research Journal* in January 2000. When the research paper was submitted, this journal refused to publish the paper, but it was published in the current *Therapeutic Research Journal* in April 2000.

*6 The results of the study were that the experimental group lost 3.14 kilograms of weight versus a 2.05 kilogram loss for the placebo group. This was a marginally statistically significant

difference according to Dr. Shi. These numbers were reached by comparing the 12 who completed the study in the control group with the 13 who completed the study in the placebo group. Using this same group comparison, Dr. Shi concluded that the study group lost 1.93 percent of body fat compared to 0.05 percent loss of body fat in the placebo group.

Table II in the Peak Wellness study used the beginning weight of all 30 subjects (including the five dropouts) to show a nine percent weight loss and a 16 percent body fat loss in the control group and a body fat loss of +1 percent by all 14 of the people who began the placebo group. Comparing -16 and +1 is the basis of the claim of 1700 percent greater fat loss. Dr. Shi's conclusion of 1.93 percent versus 0.05 percent is the basis of the claim of 3860 percent greater fat loss.

The fallacy of the percentages is exemplified by comparing -16 percent with +1 percent. There is no way those percentages can equal a 1700 percent difference, no matter what mathematical calculation one does. It is impossible to compare plus and minus and get a multiple. This fallacy is illustrated by the absurdity of these comparisons. The -16 percent is based on a fat loss of approximately 4 percent, or approximately 8 pounds. The 3860 percent is based upon a loss of approximately 4 1/4 pounds. Inasmuch as the loss of -16 percent of fat was a greater weight amount, it should not result in a lower percentage differential. This illustrates the misleading nature of the 1700 percent claim.

Defendant also misstates the placebo group in Exhibit 39.3, Tab 8, by stating that the subjects who took a placebo followed the same exercise program and actually gained body fat. This is not true since the gain in body fat is obtained only by using all 14 subjects. There is no information on the dropout from the placebo group. The subjects who completed the trial presumably continued to exercise, and that group had minimal fat loss.

The text correctly pointed out the relatively low weight losses when comparing the people who had finished the study. Table 2, which is the basis for the claim in the advertisements, compared all of the people who started. This increased the weight loss from about four percent to nine percent and also substantially increased the fat loss percentages.

Both sides have presented testimony regarding the "intent-to-treat" analysis. Defendant argues that the

intent to treat means that you use all of the subjects in the baseline; i.e., all 30 subjects in the Peak Wellness test who began. This does not make sense to the Court. The intent-to-treat analysis would seem to require the researchers to attempt to follow up on the four dropouts and then use the data from all 16 in the original group. This was not done and there is no evidence that the Peak Wellness protocol was intent to treat. Since the data was not available from the four who dropped out, there is no justification for using all 16 when comparing to the placebo group. Similarly, using all 14 who started in the placebo group is not justified. Therefore, the claim of 1700 percent fat loss difference and the nine percent weight loss difference are misleading.

*7 Dr. Shi did not compare the 16 to the 14, but rather compared the 12 who finished to the 13 who finished. He had data on all 30, but did not attempt to compare them. It appears that Mr. Kalman went through and picked and chose the data which would give the most favorable results. Mr. Kalman admitted it would have been more accurate to have compared the 12 to 13, which gives a significantly lower reduction in weight for the study group and a significantly lower differential between the two groups.

The Court can only conclude that the money being paid to Dr. Colker caused him to influence Mr. Kalman and to try to create a study which justified the money being spent by defendant and which would ensure further work from defendant.

The question is whether defendant knew of this manipulation of the data. The defendant claims it relied on the information in the abstract, which it used in the advertisements. Only if the defendant did not ask any questions and blindly accepted the information in the abstract could the defendant justify using the percentages from the abstract. However, the defendant was the sponsor of the study. There were communications between Mr. Kalman and the defendant. The defendant should have, at a minimum, asked what the actual weight losses were, what the actual fat percent decreases were, and should have had sufficient information to know the misleading nature of the percentages shown in the abstract. Failure to investigate when the information was within the control of defendant satisfies the test of *People v. Forest E. Olson, Inc.* (1982) 137 Cal.App.3d 137. Even if the defendant did not have the information to know the abstract was misleading, the defendant certainly became aware of this

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information when the article was published and even before when the criticisms of the article were discussed with Mr. Kalman. Nevertheless, the defendant did not change the representations in the advertisements.

Since the TV-ad disclaimers said the average weight loss was 6.9 pounds, defendant had actual knowledge that the nine percent weight loss claim was a distortion of the results of the Peak Wellness study. Therefore, the statements of the nine percent decrease in weight are false and misleading and were known or should have been known by defendant to be so.

Defendant's position with respect to the 3860 percent or 38.6 times is that in addition to it being literally accurate, it was blessed by the judge in the Utah case brought by Basic Research. While the judge may have indicated that the math was accurate, the judge did not say it was appropriate to make this claim in advertisements, particularly in the context in which defendant used these numbers. If anything was blessed by Judge Kimball in Utah, it was the intent-to-treat analysis using the subjects including the dropouts. The defendant was well aware of the actual weight loss and actual fat loss and knew that 3860 percent was based on extremely low weight and fat losses. Therefore the defendant knew the misleading nature of the advertisements using 3860 percent or 38.6 times.

*8 Defendant was aware that percentages can be misleading, especially when based on small amounts, from the comments on the article which were conveyed by Mr. Kalman to defendant and from Dr. Ziegenfuss in an e-mail, Exhibit 1311, discussing the EMU study which showed a loss of 3.19 pounds in the control group versus a half-pound gain in the placebo group. These numbers are comparable to the four and one-quarter pound fat loss that was the basis for the 3860 percent claim. Thus, defendant was advised that the small numbers were misleading yet continued to use the 3860 percent claim.

The use of the 1700 percent is similarly misleading in that weight loss of those who completed the study is 6.9 pounds in eight weeks compared to a four and one-half pound loss in the placebo group. Since the body fat of all 16 who began the study only went down by approximately four percent, actual body fat loss would be comparable to the weight loss. What is misleading is that the actual pounds of either weight or fat lost are substantially smaller than the claims for the before-and-after subjects or the amounts people

are expected to lose as set forth in some of the advertisements. Therefore, both the 17 times and the 38.6 times claims are misleading because of the expectations raised in the minds of a reasonable consumer that these percentages apply to higher weight losses and fat losses than were demonstrated in the Peak Wellness study.

The Peak Wellness study does not justify any of the percentage comparison- between-group claims made in the advertisements. Any reasonable consumer reading these percentages would be misled.

THE EASTERN MICHIGAN UNIVERSITY (EMU) STUDY AND *XENADRINE XTREME* MAGAZINE

The only reference to the EMU study is on page 31 of the *Xenadrine Xtreme* magazine which was mailed toward the end of the class period. It says the "safety and efficacy" of Xenadrine RFA-1 was examined. This is false, as safety was not the purpose of the study. The only specific claim related to the study is "the results showed that the subjects ingesting Xenadrine RFA-1 lost significantly more weight (759%) and fat than those using the placebo without eating fewer calories or changing their carb-to-protein ratio. In addition, no negative effects were found on resting electrocardiograms or blood lipid profiles." The 759 percent calculation is based on a comparison of the weight lost in the Xenadrine RFA-1 group (minus 3.1 pounds) as compared to the placebo group (plus 0.44 pounds). The small total loss of weight in eight weeks, combined with the fallacy of comparing plus and minus numbers, makes the 759 percent claim misleading.

This claim appears in a magazine which is 50 pages long and this reference to the EMU study consists of two sentences on page 31. Further, the preceding paragraph refers to the Peak Wellness study and the 38.6 times greater fat loss claimed to have been achieved in the Peak Wellness study. The phrase 38.6 times or 3860 percent greater total fat loss appears at least five times in the *Xenadrine Xtreme* magazine. These claims, in the context of before-and-after testimonials of losing 63 pounds of body fat, 46 pounds of fat, and weight losses of 25 pounds and 45 pounds, along with letters indicating equally substantial if not greater weight losses, e.g. 100 pounds (twice), 96 pounds, and "90 pounds of pure fat," make the magazine misleading without the reference to the EMU study, as the reader would believe the 38.6 times relates to a weight loss or fat loss much greater than four pounds.

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*9 There was testimony regarding a press conference and a news release in which claims were made about the EMU study. There was no evidence that either the press conference or the news release was seen or heard by California consumers.

Therefore, notwithstanding the substantial amount of time and effort spent on the EMU study during the course of the trial, there is no need to discuss it further.

THE UTAH CASE

The parties have introduced into evidence opinions from the basic research case in Utah. The Court has reviewed those opinions, but neither of these rulings is binding on this Court. The Court notes that while there was some evidence received in the Utah case, the Utah court did not have the benefit of a six-week trial.

PUFFING

Defendant argues that the general claims are "puffery." "Puffery" is a vague or general statement on which no reasonable person would rely. To be actionable, there needs to be a "specific establishment claim." *Thompson Medical Co., Inc. v. Ciba-Geigy Corp.* (S.D.N.Y.1986) 643 F.Supp. 1190.

The Court finds that the generalized claims in the advertisements such as "revolutionary new fat burning technology astounds the bodybuilding world" (Tab 1); "The most effective fat burning compound available" (Tab 4); and "The state of the art in fat loss technology" (Tab 8) are all puffing. Therefore, these claims and the many similar claims are not, by themselves, false or misleading.

Similarly, the claim of "pharmaceutical grade" or "pharmaceutical quality" made on the labels is puffing. Most of the experts could not even determine what this claim meant, and while Dr. Belch, in his survey, was able to obtain reactions from consumers, this claim does not appear to be false or misleading. Further, the testimony of Mel Rich supports this claim.

THE BEFORE-AND-AFTER ADVERTISEMENTS

Defendant claims to rely upon the affidavits of the individuals in the before- and-after advertisements to support the before-and-after claims. In the case of Mike Piacentino, this position makes no sense.

Defendant was in possession of Exhibit 222.2, the "Candidate Progress Chart" for Michael Piacentino. This showed that on his starting the program, he weighed 229 pounds and had 21 percent body fat. That would give him a total of 48 pounds of body fat as represented. At week 10, which is the time period referred to in the advertisement, Mr. Piacentino weighed 195 pounds and had 8 percent body fat. That would give him 15 1/2 pounds of body fat. That meant that during this period, he would have lost 32 1/2 pounds of body fat, not 46 pounds of body fat as represented. Since the total weight loss was 34 pounds, he would have lost muscle mass, not gained it, to make up the difference in the total weight loss between the fat loss of 32 1/2 pounds and the total weight loss of 34 pounds. Even using the week 12 reduction to 7 percent body fat, would give a total of about 13 1/2 pounds of body fat which would account for about 34 1/2 pounds of body fat loss which means, at most, Mr. Piacentino would have gained 1/2 pound of muscle, not the 12 pounds as indicated in the advertisement.

*10 There is no way to reconcile the affidavit indicating 46 pounds of weight loss with either the calculations in Exhibit 1289.1 through 1289.13 (the documents from Physical Addiction) or Exhibit 222.2. Even the weight loss of 34 pounds is misleading because of the additional supplements being taken by Mr. Piacentino.

Since both Mr. Chinery and Mr. Conklin were aware of the inconsistent information, the claims in the advertisement regarding Mr. Piacentino's fat loss and muscle mass gain are evidence of defendant's willingness to stretch the truth to make its product appear to be more effective than it actually was. Both Mr. Chinery and Mr. Conklin used the identical wording that they were "confused" by the chart of the weight loss which showed only a 34-pound weight loss and the affidavit which showed a 46-pound weight loss. Yet the advertisements claim a fat loss of 46 pounds plus a 12-pound gain of muscle. Therefore, the defendant could not be relying on the affidavit which says a weight loss of 46 pounds. If the public does not know the difference between fat loss and weight loss as argued by the defendant, it would think from the advertisement that there had been a 46-pound weight loss. Since the defendant knew there had only been a 34-pound loss, the defendant knew this claim was false.

Evidence was introduced in the form of testimony from Mike Piacentino and documents from Physical

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Addition that the weight losses attributable to Karen Curtis, Remy Feniello and Maria Korsgaard were not accurate. There is no evidence that defendant had this information. For each of these individuals defendant produced an affidavit attesting to accuracy (Exhibits 2118, 2120 and 596). There is no evidence that defendant knew that the affidavits were inaccurate. While there is some question about the notarization of the affidavits, as they are all notarized by the same notary, and none of the affidavits has a date by the notarization, this by itself is not enough to invalidate the affidavits. More importantly, since the before-and-after ads are misleading in the context of the exaggerated claims of fat loss, whether the before-and-after ads are accurate is not significant. The advertisements are misleading in that the typical consumer would expect dramatic weight losses based not only on the before-and-after ad but on the percentage fat loss claim, which a reasonable consumer would think bears some relationship to the amount of weight lost as shown in the before-and-after ads. Since the actual amount of fat loss, which forms the basis for the percentage claims was so small, the advertisements are misleading.

In the case of Randy Martin his letter says his transformation was five months (Exhibit 1070) rather than the three months claimed in the advertisements. Defendant says Mr. Martin clarified the time later and said the weight was lost in three months. Since the weight loss by Mr. Martin is so great, there would be little reason to exaggerate the time it took, and therefore, the Court does not find the claims of weight loss by Randy Martin to be misleading. Compare, Christine Muller "45 pounds in 16 weeks" (Tab 13, Exhibit 19) with television Clip 5, Christine Muller "45 pounds in 12 weeks" with Clip 6, Christine Muller "41 pounds in 12 weeks."

CREDIBILITY

*11 Before discussing the specific advertisements, it is necessary to discuss the credibility of the defendant's most important witness, Robert Chinery, the president of defendant. He worked for Pro Source and then left and started Cytodyne. He developed Xenadrine RFA-1. The Court does not find Mr. Chinery to be credible. Similarly the witnesses on defendant's payroll or retainer, *e.g.*, Kelly Conklin, Dr. Ziegenfuss and Dr. Colker, were not credible.

This finding is particularly important in evaluating what the defendant knew about the claims it was making. The Court finds the defendant was well

aware that the claims made in the early ads were not accurate, as Mr. Chinery knew Xenadrine RFA-1 had not been the subject of the studies, knew only portions of the ingredients had been studied, and knew of the different dosages. Since Mr. Chinery was drafting the advertisements, it was his language that was designed to mislead consumers reading the advertisements by making a reader think that Xenadrine RFA-1 had been tested.

With respect to the Peak Wellness study, the Court finds Mr. Chinery was well informed of what was going on, and that he understood the actual amounts of weight and fat losses in the study. It appears that he probably encouraged Mr. Kalman to use the numbers that exaggerated the results.

With respect to the before-and-after studies, there is no specific evidence that Mr. Chinery was aware that the weight losses might have been exaggerated, other than Mike Piacentino. However, given his experience in the field, he probably knew that the affidavits were not accurate. He knew about Mike Piacentino because he knew about the candidate weight-loss chart, and he should have known that Mr. Piacentino had previously posed for an advertisement for Pro Source as a well-conditioned body builder before he underwent his "transformation" using Xenadrine RFA-1 (See Exhibit 93.48).

Mr. Chinery's lack of candor can be seen throughout the trial.

Cytodyne has consistently failed to produce documents that could have explained things, pushed researchers to make studies come out favorable to them and paid money to the key people involved in providing information to them to ensure the information was favorable to them.

The discovery responses on the sales in California seem to have been designed to mislead the plaintiff. The defendant did not have any product complaints before 2000. There were no certificates of analysis. There were no assays. E- mails were deleted. Peak Wellness did not have its underlying documents. Mel Rich did not bring documents. Mr. Schiff did not bring documents, and some affidavits appear to be missing from the before-and-after subjects.

In addition, there are a series of mistakes, each favorable to defendant. There are mistakes in the p-values in the Peak Wellness study. There is a mistake on the website. There was a mistake in citing the

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wrong journal as support in one of the advertisements. There was a mistake in the weight-loss claims. There was not a patent pending.

*12 Defendant's entire approach to marketing Xenadrine RFA-1 is epitomized by Dr. Armstrong at page 188, line 8 of his deposition when he said that what he was signing was "not a lie, per se."

SAFETY

A substantial amount of the trial was spent with experts on both sides testifying regarding the safety of Xenadrine RFA-1 or the safety of ephedrine and ephedrine caffeine products. The issue of safety is relevant to the express and implied claims of safety.

The Court first notes that while there should be substantial additional investigation into any adverse event reports and whether adverse reactions may be caused by Xenadrine RFA-1 or the other ephedra products on the market, it is not the role of this Court to determine whether or not this product should be banned. The plaintiffs do not seek to ban Xenadrine RFA-1 from market, nor would it be within the power of this Court pursuant to the provisions of California Business and Professions Code section 17200 to make such an order. Any regulation is within the purview of the regulatory agencies and the legislature. The Court is ruling on the issue before it in this action: whether defendants have engaged in false and misleading advertising.

There have been numerous complaints submitted to defendant, to competitors of defendant, and to the Food & Drug Administration from consumers who claim they have suffered everything from transient events, such as palpitations or high blood pressure to strokes and heart attacks, some resulting in death. The Court allowed these adverse events into evidence, but only for the purpose of showing that the complaints had been made. There was no evidence that the complaints were truthful, i.e. that the events had in fact occurred, and no proof of any causal connection between taking Xenadrine RFA-1 or other ephedra products and the adverse event, although some of plaintiff's experts testified to a connection and pointed out the nature of ephedrine and caffeine is to constrict blood vessels and raise heart rate, which results in higher blood pressure, higher body temperature which, when combined with exercise, can result in stroke and heart attacks.

Even though there have been hundreds and maybe

thousands of complaints regarding ephedra products, no evidence was introduced of the number of complaints including strokes and heart attacks that occur in the general population nor of the number of ephedra users. Thus, the ratio of complaints among ephedra users could not be compared to the general population. Recently, the *Rand Report* was published. While it was referred to by some of the experts, it was not allowed into evidence and the Court did not consider its conclusions.

It appears that defendant has gone out of its way to minimize the existence of any health risks that might exist. An example of this is in the *Xenadrine Xtreme* magazine. The thermogenics article by Dr. Ziegenfuss originally contained language on the last page under the heading, "Take Home Messages" that recommended using the product for only four to eight weeks and pointed out that one could expect certain side effects such as trembling, jitters, and elevated heart rate. These health warnings were edited out and do not appear in the article that was published in the *Xenadrine Xtreme* magazine. (Exhibit 281.7, Exhibit 2083, p.13).

*13 In light of the questions as to the safety of ephedra products and the lack of safety studies, the Court finds that Tabs 1, 3, 4 and 8 are misleading because of the implied safety claims. The testimonials from doctors in Tabs 1, 3, 4 and 8 imply Xenadrine RFA-1 is safe, as does the reference in Tabs 1 and 3 to "outperforming dangerous prescription products." This finding is in addition to the reasons discussed below that these advertisements are misleading. The safety statements in the *Xenadrine Xtreme* magazine are false in that the safety of Xenadrine RFA-1 had not been studied.

THE GENERIC STUDIES

The generic studies referred to in Tabs 1-6 and labels 1-3 do not support the claims made in the advertisements or the labels. References to these studies are misleading in that Xenadrine RFA-1 was not tested; the Xenadrine RFA-1 formula was not tested; the dosages in some studies are different; some studied rats, not humans; and the ingredients are not identical, e.g., some include aspirin (not salicin), some include only L-tyrosine, some tested only ephedrine; some tested ephedrine and caffeine, and some studied synthetic rather than botanical ephedrine. None of these differences are explained. Therefore, it is misleading to make it appear that Xenadrine RFA-1 was tested.

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THE PRINT ADVERTISEMENTS

The Court will now discuss the effectiveness claims in individual advertisements.

TAB 1 [FN1]

FN1. The Court has admitted the notebook containing the advertisements with Tabs 1-15 as Exhibit 2393.

The very first ad, Tab 1, Exhibit No. 94.3, has several false and misleading statements. The ad says: "Shown in studies to increase the rate of fat loss by up to 300 percent!" Dr. Krieger, who did the study, testified this claim was false because the study did not measure fat loss but only weight loss. Moreover, the clear implication is that this weight loss relates to the product being advertised, Xenadrine RFA-1, particularly since it says, "New. Available without a prescription" in the corner above this phrase. The amounts of weight loss of the two models are 68 pounds in 10 weeks and 57 pounds in 9 weeks. The footnote in very small print says, "Joseph Isnardi (sic) and Nancy Latarroca achieved their extraordinary results using Xenadrine RFA-1 as their exclusive dietary supplement to their training program." A reasonable consumer would assume, even though these were extraordinary results, that he or she might achieve results at least in the ballpark of the weight lost by these two models.

The phrase, "Patent Pending pharmaceutical grade formula," is false in that there was no patent pending. Whether this is a mistake or not, it certainly is a mistake in favor of defendant and given defendant's tendency throughout to exaggerate and always use the claim most favorable to it irrespective of the contraindications, the Court finds that phrase is false and misleading. It further adds to the misrepresentation as to whether Xenadrine RFA-1 was being tested. Why would this formula have a patent pending on it if it were not the formula that was being tested?

*14 On the right-hand side of the advertisement, there are statements from doctors juxtaposed with statements such as "Shown in clinical studies to be 29% more effective...." Without any other reference, it appears that it was Xenadrine RFA-1 that was shown to be more effective. The next statement is: "Unlike other weight loss products, Xenadrine RFA-1's thermogenic activity is not decreased the longer you use it. To the contrary, Xenadrine RFA-1's

potent thermogenic fat burning effects actually increase," followed by a citation to Astrup. This refers to Xenadrine RFA-1's thermogenic activity, not the ingredients in Xenadrine RFA-1 and since Astrup tested only generic compounds, this statement is misleading. The next quote is "Xenadrine RFA-1's advanced thermogenic formula has been shown to actually spare lean muscle tissue...." The citation again is misleading because it appears that Xenadrine RFA-1 was tested. Finally, the quote, "has been shown to actually prevent regaining of body fat normally associated with extreme weight loss," with a citation to Astrup must mean Xenadrine RFA-1 because there is no other reference. Thus, the first advertisement is misleading.

TAB 2

The second print advertisement, Tab 2, Exhibit 94.2, "Revolutionary new fat burning technology astounds the bodybuilding world," has quotes from bodybuilders which were not challenged during the litigation. In the right-hand column, the ad says:

Since its introduction to the body building scene, Xenadrine RFA-1 has already established itself as the most effective of this emerging generation of sophisticated scientific weight loss tools! Xenadrine RFA-1's potent thermogenic combination has been proven in more scientific studies than virtually any other formula (prescription or non-prescription). But Xenadrine RFA-1's powerful effects don't stop there-in a ground breaking study published in the prestigious International Journal of Obesity this potent thermogenic compound was actually shown to spare lean muscle tissue during intense weight loss cycles*, making Xenadrine RFA-1 the ultimate physique transformation tool!

*Pasquali R, et al. Chronic beta receptors stimulation prevents nitrogen loss during semistarvation in obese subjects. International Journal of Obesity 13 (supplement 1): (abstract).

The second advertisement is misleading in that a reasonable consumer would think Xenadrine RFA-1 was the product tested.

TAB 3

The third print advertisement, Tab 3, Exhibit 58, is virtually identical to the first ad except that the before-and-after substitutes Farah Fabricatore for Chris Sorrentino. Ms. Fabricatore lost 39 pounds in 28 days. This advertisement adds the phrase, "Lose up to 30 pounds in 30 days with the most powerful fat

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burning compound ever developed." It has all of the false and misleading claims of the first advertisement, but by adding the phrase, "30 pounds in 30 days," it is even more misleading.

TAB 4

*15 In Tab 4, Exhibit 97, the truth of the portion of the advertisement with quotes from the doctors is unchallenged by the plaintiffs. Other than safety, the only portion which could be deemed misleading is the portion that talks about the scientific references. It says that the formula "is centered around a highly advanced, research proven thermogenic compound...." It then says, "Xenadrine RFA-1's revolutionary thermogenic compound has been proven effective through a vast series of scientific studies which offer irrefutable proof to the extraordinary fat-burning/muscle sparing effects that are possible. No other thermogenic formula is backed by this number of published scientific studies!"

The clear implication of the second portion is that Xenadrine RFA-1 has been proven effective in scientific tests because no other thermogenic formula is backed by this number of tests. Further, since Xenadrine RFA-1 "is a revolutionary new approach to weight loss ... based on the latest scientific research," any reasonable consumer would believe Xenadrine RFA-1 is the subject of the research mentioned in the list of scientific references. Therefore, TAB 4 is misleading.

TAB 5

The fifth advertisement, Tab 5, Exhibit 98.2 "Clinical studies confirm Xenadrine RFA-1's amazing fat-burning/muscle-sparing effects" is a two-page advertisement. The first page consists of before-and-after pictures of Randall Hanson stating that he lost "an extraordinary 63 pounds of body fat." The plaintiffs have not challenged any of the claims attributed to Mr. Hanson.

The next page, Exhibit 98.3, has four pictures on the top of bodybuilders with quotes attributed to them. The plaintiffs do not challenge this portion of the advertisement. The right-hand side consists of quotes from articles praising Xenadrine RFA-1 that are not challenged by plaintiff. Plaintiff challenges the portion on the left-hand column of the second page which states,

Clinically Proven To "Burn Fat and Spare Muscle" Xenadrine RFA-1's advance "E/C"

thermogenic combination has been the subject of numerous published clinical studies which offer undeniable proof of the extraordinary fat-burning/muscle sparing effects that are possible. In a recent study published in the prestigious *International Journal of Obesity*, this potent compound was shown to *increase the metabolic rate by over an astounding 600%!* This same journal also published a study showing the synthetic equivalent of this compound to *increase the total rate of fat-loss by over 300%!* And in yet another groundbreaking study, this potent compound was shown to help *prevent regaining of bodyfat* that is typically associated with extreme weight loss. This remarkable feat is actually made possible by way of Xenadrine RFA-1's amazing muscle sparing effects. In other words, preserving lean muscle tissue which is more 'metabolically active' than fat, the body is left with a permanently increased metabolism which in effect burns more calories and prevents new fat stores from forming.

*16 Another study published in the *Journal of Pharmacology and Experimental Therapeutics* found that by adding a specific thermogenic synergist, this combination may become over *54% more effective* than virtually any other thermogenic formula on the market." (All emphasis in original.)

No other thermogenic combination is backed by this number of published clinical studies!

The heading "Clinically Proven," followed by references to clinical studies, is misleading in that the reader would think that it was Xenadrine RFA-1 that had been clinically proven, not merely some ingredient. Since none of the studies relate to Xenadrine RFA-1, all of the claims except for the 300 percent attributed to "the synthetic equivalent" are misleading (and Dr. Kreiger said only weight loss was studied.) There is a claim that by adding a specific thermogenic synergist, the "combination may become over 45% more effective than virtually any other thermogenic formula on the market." The Maher study does not appear to support this claim. Further, Dr. Maher testified that his study did not support this conclusion. Even though Dr. Maher is probably biased against the defendant, the Court concludes that this portion relating to the Maher study is misleading.

OTHER ADVERTISERS

Before discussing the rest of defendant's advertisements, the Court will address the defendant's argument that its claims are not misleading in light of

competitors' claims. Defendant has introduced two magazines for the Court to review to see the context in which readers see the Xenadrine RFA-1 ads. Exhibit 2376 is *Flex Magazine* from March 1998 and Exhibit 2377 is *Musclemag International* for February 2000. Both magazines consist of articles on bodybuilding and bodybuilding contests with seemingly an equal amount of advertising, primarily for supplements designed to add muscle or lose fat. The supplement business appears to be highly competitive. The defendant is correct in that consumers are bombarded with numerous advertisements and many claims of benefit for these products. A careful review of the advertisements, however, shows that the advertisements for Xenadrine RFA-1 make more specific claims than all but a couple of the other advertisements.

Even those advertisements with specific claims are far more candid than defendant's advertisements. For example, Hydroxycut makes a claim that you can burn 613 percent more fat, but in the text, it refers to "the highly touted ECA (Ephedrine, caffeine and aspirin) stack. This very stack is found in Hydroxycut and has been shown in recent clinical study to elicit a 613 percent greater rate of fat loss...." (Exhibit 2377, p.3). The advertisement makes it clear that they are referring to the ingredients in Hydroxycut and not Hydroxycut itself. The Hydroxycut ad goes on to discuss the other ingredients in Hydroxycut and their added benefits, thus making it clear that Hydroxycut was not the subject of the study. Further, the advertisement refers to body fat loss in pounds and shows Group 1, the control group, lost 1.5 pounds whereas Group 2 "ECA stack as found in Hydroxycut" lost 9.2 pounds. Thus, the reader is able to see the actual weight loss being claimed.

*17 By contrast, the advertisements for Xenadrine RFA-1 say, "Xenadrine RFA-1's revolutionary thermogenic compound has been proven effective through a vast series of scientific studies ... no other thermogenic formula is backed by this number of published scientific studies." Other claims are that Xenadrine RFA-1's advanced "E/C thermogenic combination has been the subject of numerous published clinical studies ... in a recent study published in the prestigious *International Journal of Obesity*, this potent compound was shown to increase metabolic rate by over an astounding 600 percent."

As a result, any reasonable consumer would believe that Xenadrine RFA-1 has been tested in the scientific journals cited in the advertisements. Notwithstanding

the word, "new," there is no way for a reasonable consumer to know that the product did not exist in the early '90s when some of the *Journal* articles were published. While a skilled grammarian or a skilled lawyer might find ambiguities in the language to show that it does not specifically say that Xenadrine RFA-1 was tested, that is not a reasonable conclusion for a reasonable consumer. Defendant's ads are written to leave the reader with the impression that it was Xenadrine RFA-1 that was tested. As is shown in the Hydroxycut ads, it is very simple to state that it is the ingredients, or at least some of the ingredients, that were tested in these studies. [FN2]

FN2. The Court is not finding the Hydroxycut advertisement to be accurate. It is only being used to show that the competitors are giving consumers more information about the studies.

Contained in Exhibit 2377 is an advertisement for another Cytodyne product called Cytoplex." This advertisement says that Cytoplex contains a revolutionary compound called "Glucostatin-RFS" which is made up of a unique blend of substrates *clinically proven* to stimulate rapid and dramatic weight loss results, even without dieting." (Emphasis in original.) It also refers to an article in the *International Journal of Obesity* that found Glucostatin substrate number one actually increased the rate of weight loss by over 600 percent.

The Court finds this advertisement significant in two respects. First, it shows that defendant is capable of writing an advertisement that makes it clear that only the ingredients have been tested in scientific journals and not the product itself. Second, this appears to be one of the products that Randall Hanson provided to Mike Piacentino and possibly some of the other before-and-after subjects. Since this product is designed to increase weight loss, it would be extremely significant to a before-and-after subject who claims to have lost weight due to Xenadrine RFA-1. There is no way of knowing whether the weight loss was due to Xenadrine RFA-1, to Cytoplex, to the other supplements, or to the incredible workouts done by Mr. Piacentino. The failure to disclose the consumption of other supplements is another reason the Mike Piacentino before-and-after advertisements are misleading. Therefore, the Court does not need to resolve the factual disputes regarding the photographs or the instructions given to Mr. Piacentino.

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*18 Since the supplements came from Cytodyne to Mr. Hanson, defendant cannot claim it did not know that these supplements were being provided to the before-and-after subjects. Defendant argues that Mr. Hanson was doing before- and-after studies on many different products and, therefore, defendant would not know that subject was getting which supplements that defendant provided to Mr. Hanson. The defendant should have known that Mr. Hanson was providing Mr. Piacentino with additional supplements, including supplements that were used as meal substitutes and therefore were used in losing weight. Had defendant done any investigation, such as simply asking Mr. Hanson (who was being paid by defendant as a consultant) who was receiving which supplements, it would have discovered this fact. See *People v. Forest E. Olsen* (1982) 137 Cal.App.3d 137.

TAB 6 and TAB 7

Exhibit 40, Tab 6, and Exhibit 2371, Tab 7, "Take Control," feature Nancy Latarocca losing 57 pounds in nine weeks. Tab 6 says, "It is no wonder Xenadrine RFA-1 is America's hottest new diet product. This revolutionary formula is centered around an advanced thermogenic compound shown in clinical studies to increase the metabolism and the total rate of fat loss by over 600 percent."

Tab 7, after an identical first sentence says, "In a groundbreaking double blind clinical trial, Xenadrine RFA-1's revolutionary thermogenic formula was shown to increase the rate of fat loss by a phenomenal 1700%!" (Emphasis in original.) Defendant used virtually the identical language in Tab 7 to refer to a study on Xenadrine RFA-1 as it used in Tab 6 to describe generic studies. This illustrates how the reference in Tab 6 is misleading, as anyone reading Tab 6 would think it was Xenadrine RFA-1 that was tested.

Tab 7 has a disclaimer, "While Nancy's results were extraordinary and go beyond what the average person may achieve, Xenadrine RFA-1 guarantees visible weight results in just 30 days or your money back." However, there is no indication that Nancy's results are six or seven times greater than the results achieved in the Peak Wellness study. The 1700 percent claim is misleading and it is not saved by the disclaimer.

TAB 8

With respect to Tab 8, Exhibit 39, the middle page appears to be the first print ad to state in bold letters, as a headline, "Clinically proven to increase fat loss by an unprecedented 1700 percent." This advertisement contains both the 1700 percent greater fat-loss claim and the claim that the subjects reduced their total body weight by a remarkable nine percent. Both of these claims are misleading for the reasons discussed in the discussion of the Peak Wellness study.

The 1700-percent and nine-percent claims are also misleading in the context of the advertisement showing Mike Piacentino with a 46-pound loss, which is substantially greater than the weight loss in the Peak Wellness study. Further, as previously discussed, Mr. Piacentino's weight loss was not 46 pounds, nor did he drop 46 pounds of fat while "packing on a phenomenal 12 pounds of lean muscle mass." Further, any before-and-after advertisement with Mr. Piacentino is misleading because it does not disclose the use of other supplements and, in particular, meal-substitute supplements.

TAB 9

*19 Tab 9, Exhibit 41, "You can see the difference" says Lisa Debonis lost 48 pounds in 12 weeks and although "Lisa's results are not typical," the statement that Xenadrine RFA-1 is "clinically proven to increase fat loss by an astounding seventeen times more than diet and exercise alone" (38.6 times in later ads) would indicate that the clinical proof should have been more substantial than the four pound fat loss in eight weeks that was basis of the 38.6 times claim or the 6.9 pound actual weight loss. Therefore, the advertisement is misleading.

TAB 10

Tab 10, Exhibit 52.5, features Maria Korsgaard and claims she lost an extraordinary 25 pounds in just three weeks. Even though her results are "not typical," the claim that Xenadrine RFA-1 is "clinically shown to increase fat loss by an astounding 38.6 times more than diet and exercise alone" is misleading in this context since 25 pounds in three weeks is so dramatically higher than the 6.9 pounds in eight weeks that was shown in the Peak Wellness study.

TAB 11

Tab 11, Exhibit 51, featuring Karen Curtis (24

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pounds in three weeks), Dave Muller (30 pounds in three weeks), and Maria Korsgaard (25 pounds in three weeks) refers to Xenadrine RFA-1 having been "clinically proven to increase fat loss by a phenomenal 17 times more than diet and exercise alone!" This claim of is followed immediately by, "Whether you need to lose 15 pounds or 100." Thus, anyone reading this ad would think that the 17-times loss bears some relation to weight losses of 15 pounds to 100 pounds or to the weight losses of these models. Therefore, Tab 11 is misleading.

Tabs 9, 10, 11, 13, and 14 refer to *weight loss* in the before-and-after pictures and then make claims about *fat loss*. This appears to be an intentional attempt to exaggerate the claims. The weight loss percentage differences in the Peak Wellness test were substantially lower than the fat loss percentage differences between groups. The defendant has argued, and from these advertisements it appears the defendant believes, the public confuses fat loss with weight loss. Yet the advertisements use percentage fat loss claims to make it appear that weight loss also will be dramatically higher for those using Xenadrine RFA-1 compared to those using diet and exercise alone. This is one more example of how these advertisements are misleading.

TAB 12

The advertisement with Marshall Faulk, Tab 12, Exhibit 21, contains a claim of 3860 percent greater total fat loss which is misleading. However, the small amount of space devoted to this claim compared to the two pages of quotes, statistics and pictures of football stars makes this claim, in context, immaterial. It is doubtful if a reasonable consumer would be persuaded by the fat loss claim when there is no mention of any of the athletes losing specific amounts of weight or fat. The thrust of the advertisement is that Xenadrine RFA-1 will improve performance and make you look better, not that you will lose a specific amount of weight or fat. Therefore, the fat loss claim is not material and this ad is not misleading.

TAB 13

*20 Tab 13, Exhibit 67 contains the phrase, "Clinically proven to increase fat loss by a phenomenal 38.6 times more than diet and exercise alone" claim. (Emphasis in original.) As previously discussed, the 38.6 times by itself is misleading and in the context of before-and-after claims of losses of 54 pounds and 45 pounds, the 38.6 times claim is

even more misleading. It is not saved by the phrase, "These results not typical" because the typical results are not shown.

The only time the actual results were shown was in the television commercials. There was a statement on the screen that the average weight loss was 6.9 pounds in 8 weeks. The Court is unable to find such a disclaimer in any of the print ads. The defendant was aware of the actual weight loss and knew it should be letting people know the average weight loss, yet the defendant did not use the actual average weight loss in any of the print ads where it would be more likely to be read than in the television ads.

TAB 14

The last advertisement, Tab No. 14, Exhibit 20, "What a difference," suffers from the same distortion as the other advertisements with the 38.6 times claim in the same advertisement with a claim of extraordinary weight losses, in this case, Remy Feniello's claim of losing 35 pounds in four weeks. Therefore this advertisement is also misleading.

TELEVISION COMMERCIALS

Each side has submitted transcriptions of the television advertisements that ran during the class period for Spots or Clips 2, 3, 4, 5, 6, 7, 10, 11 and 12. The plaintiff has also inserted clip 8. As the Court is not certain when clip 8 ran, it is not included in this analysis. Spot or Clip 2 and Spot or Clip 12 are in Spanish.

As to Clips 3, 4, 5, 6, 7 10 and 11, each contains the claim of "Clinically proven to increase fat loss 38 times more than diet and exercise alone." As discussed in the analysis of the Peak Wellness study and the print ads, this claim by itself is misleading. This claim is even more misleading in these television advertisements, each of which contained a claim of substantial weight loss by the before-and-after models. Therefore, I find each of the English television commercials to be misleading.

In virtually unreadable small print on the bottom of the picture in the television advertisements, there is a statement that appears for a very brief time that the average weight loss was 6.9 pounds in 8 weeks. Further, anyone watching the television screen is so distracted by the men and women moving around, there is very little likelihood that any reasonable consumer would read the disclaimer. The defendant's

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statements that it was attempting to have visible disclaimers in the television ads are disingenuous and the disclaimers do not cure the misleading nature of the ads.

With respect to the Spanish version (Clip 2), the before-and-after claims are the same, but there are no disclaimers. Clip 2 contains a claim of 1700 percent greater loss of weight. This is misleading for the reasons discussed in the analysis of the Peak Wellness study and particularly in the context of the substantial weight losses in the before-and-after claims. Further, the 1700 percent, if it was accurate, only applies to fat loss, not weight loss.

*21 Clips 2 and 3 use Mike Piacentino and are also misleading for the reasons discussed in the before-and-after section.

The final television clip or spot, Number 12, merely contains before-and-after claims, which are not by themselves misleading. Since there does not appear to be a specific percentage claim in this commercial, it is not misleading.

THE LABELS

The first Xenadrine RFA-1 label says "Xenadrine RFA-1's advanced new thermogenic formula represents the most sophisticated natural weight loss technology available. Its powerful thermogenic combination has been proven effective in numerous scientific studies." Exhibit 2006. Various articles are cited to support this. Clearly the import is that Xenadrine RFA-1 was tested. The second label, Exhibit 2007, made a slight change by adding "E/C" so the second sentence read, "Its powerful E/C thermogenic combination has been proven effective in numerous scientific studies." The listing of the generic studies has been deleted, but that does not cure the implication that Xenadrine RFA-1 had been tested. The same language is contained in label number 3, Exhibit 2004.

In analyzing the effect of the claims on the labels that it was Xenadrine RFA-1 that had been tested rather than merely a component, the survey done by Dr. Belch is helpful. I find that the Belch survey is a valid survey and the Court is not persuaded the criticisms of Dr. Strand.

In response to a question on labels 1, 2 and 3, the Belch survey showed that 56 percent of the people responding felt that Xenadrine RFA-1 had been

proven effective in scientific studies (Exhibit 1305).

After the Peak Wellness study, the label was changed in the fall of 1999, to read, "Xenadrine RFA-1's advanced new thermogenic formula represents the most sophisticated natural weight loss technology available. Its powerful fat loss/muscle sparing effects have been documented through published clinical research." Exhibit 2005. Anyone comparing the language in the first three labels and the language in Exhibits 2005, 2009 and 10.5, the last three labels from fall 1999 through the end of the class period, would not be able to tell the difference. The language is virtually the same in the way it refers to what has been studied and tested and with reference back to Xenadrine RFA-1. While the last three labels are correct insofar as Xenadrine RFA-1 itself had been tested, the first three labels are not, and are misleading.

The last three labels are accurate in that Xenadrine RFA-1 was studied and fat loss and muscle sparing results were documented. No specific claims are made as to the results. Therefore, only the first three labels are misleading. The phrase "clinically proven" by itself is not misleading, nor is "thermogenic."

WARNINGS

The label has warnings for people with high blood pressure, and various other conditions. Even though consumers may not know they have the conditions, the warning advises them to consult a doctor if they are at risk or have a family history of the listed conditions in the warning. The Court finds that the warning on the last label is not misleading and no injunctive relief will be granted with respect to the label.

CLAIMS REGARDING THE CONTENT

*22 Plaintiff has challenged the amount of the ingredients, their purity and specifically challenge the amount of salacin. Defendant produced Mr. Rich, the owner of Phoenix Laboratories who was a very persuasive witness, even though he did not bring documents. They also produced Mr. Schiff regarding the methods of verifying the amounts of the ingredients.

Plaintiff's experts came up with different results based on testing very small amounts of the product. Since plaintiff has the burden of proof of proving the claims to be false, the Court finds that plaintiff has

not carried this burden.

REMEDY

A. The Consumer Legal Remedies Act

As set forth in Civil Code section 1782, the Consumer Legal Remedies Act (CLRA) requires that "thirty days or more" prior to filing a CLRA action "for damages" the consumer "shall" notify the potential defendant "of the particular alleged violations of Section 1770" and demand that he or she "correct, repair, replace or otherwise rectify" the goods or services alleged to be in violation of Section 1770.

The purpose of this notice is to provide and facilitate pre-complaint settlements of consumer actions wherever possible and to establish the limited period during which such settlement may be accomplished. *Outboard Marine Corp. v. Superior Court* (1975) 52 Cal.App.3d 30, 41.

A party can amend a complaint for injunctive relief to allege damages. Subsection (d) provides: "Not less than 30 days after the commencement of an action for injunctive relief, and after compliance with subdivision (a), the consumer may amend his or her complaint without leave of court to include a request for damages." Under this section, the amendment must be filed "not less than 30 days after commencement of the action for injunctive relief."

The notice requirements under the CLRA are to be "literally applied." *Outboard Marine Corp.* at 41. In *Outboard*, plaintiff argued "substantial compliance", in part, because of a letter sent several months after the complaint was filed. The court held that literal interpretation was the only means to comply with the purpose of facilitating pre-settlement negotiations. However, the court upheld the trial court's order overruling the demurrer. The court found that defendant effectively waived the notice provisions in a responsive letter whereby defendant indicated they construed the letter "as a preliminary notice and demand under California Civil Code 1782(a)." The court held that this statement constituted a waiver of a known right.

In the case at bar, the Complaint was filed on June 4, 2001. Paragraph 62 includes an allegation for damages. However, the letter giving notice was not sent until August 29, 2001. The letter giving notice did not comply with Civil Code section 1782, which requires the letter to be sent 30 days prior to the

commencement of the action and a First Amended Complaint was never filed.

Defendant did not waive the notice requirement. The stipulation attached at Exhibit 7 merely indicates that plaintiff is seeking damages contained in Plaintiff's Statement of Damages dated October 29, 2001. There is no statement that plaintiff and defendant agree that any damages are allowable under the CLRA cause of action or that the damages in the stipulation are sought under the CLRA.

*23 A demurrer was filed based, in part, on the failure to provide notice of the CLRA. However, the fact that Judge Hayes overruled the demurrer does not mean that the cause of action is proper. Judge Hayes made no finding that the notice was given or was not required. He only overruled the demurrer. The failure to state a cause of action is never waived. (Code Civ. Proc., § 430.80(a)).

Based on the above, plaintiff did not properly comply with the requirements in the CLRA for damages. Thus, damages are not awardable under the CLRA.

Even if the requirements of the CLRA had been met, the only evidence regarding damages is the amount the members of the class paid for the product. There is no evidence of the value of what the class members received. In order to award damages, the Court would have to compare the difference between what the class members paid for the product and the value of the product they received. (Civ.Code, § 3343). The Court has no evidence upon which to make such a finding. Since there is no evidence that the product has no value, the plaintiff would not be entitled to damages under the CLRA.

B. Monetary Remedy

In fashioning a remedy under the unfair competition law, section 17203 does not mandate restitutionary or injunctive relief, rather it provides that the court "may make such orders or judgments ... as may be necessary to prevent the use or employment ... of any practice which constitutes unfair competition ... or as may be necessary to restore to any person in interest any money or property ... which may have been acquired by means of such unfair competition ." Thus, the court has broad equitable power to create a remedy. *Cortez v. Purolator Airfiltration Products Co.* (2000) 23 Cal.4th 163, 179.

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With this in mind, the Court will first discuss monetary remedies. Plaintiff argues that the class should recover the entire purchase price of Xenadrine RFA-1 from Cytodyne. Defendant argues that, at most, the plaintiff should only recover the "net profit."

The cases analyzing the unfair competition law (UCL) use the term "restitution" as well as "disgorgement" to describe the remedy available. A precise definition of terms is necessary.

Restitution has been defined as "compelling the UCL defendant to return money obtained through an unfair business practice to those persons in interest from whom the property was taken, that is, to persons who had an ownership interest in the property." *Korea Supply Company v. Lockheed Martin Corporation* (2003) 29 Cal.4th 1134, 1144-1145; citing *Kraus v. Trinity Management Services, Inc.* (2000) 23 Cal.4th 116, 126-127. True restitution recaptures the direct gain obtained by defendant in order to prevent unjust enrichment.

Disgorgement is a remedy that is broader than restitution. Disgorgement may be a synonym for restitution, but more often than not, disgorgement refers to a remedy for those who were not direct victims of an unfair practice. In this nonrestitutionary sense, disgorgement requires the surrender of all profits earned as a result of an unlawful practice regardless of whether those profits represent money taken directly from persons who were victims of the unfair practice. *Korea Supply* at 1145. After *Korea Supply*, there is an issue as to whether disgorgement in this "nonrestitutionary" sense is allowable under the UCL.

*24 Whether one is talking "true restitution" or "disgorgement," the measure is based upon defendant's benefit and not plaintiff's losses. The language of Business and Professions Code section 17203 contemplates that the money or interest was acquired by means of the practice. Both restitution and disgorgement involve a return of what defendant gained in the transaction. A party seeking restitution "must generally return any benefit" that it has received. Rest.2d, Contracts, § 376, com. a, § 384, com. a.) *California Federal Bank v. Matreyek* (1992) 8 Cal.App. 4th 125.

The purpose behind Business and Professions Code section 17200 is deterrence and not punishment. The purpose is "to deter future violations of the unfair

trade practice statute and to foreclose retention by the violator of its ill-gotten gains." *Fletcher v. Security Pacific National Bank* (1979) 23 Cal.3d 442. The court in *Korea Supply* discussed the purposes of the statute in terms of deterrence:

The language of section 17203 is clear that the equitable powers of a court are to be used to "prevent" practices that constitute unfair competition and to "restore to any person in interest" any money or property acquired through unfair practices. (§ 17203.) While the "prevent" prong of section 17203 suggests that the Legislature considered deterrence of unfair practices to be an important goal, the fact that attorney fees and damages, including punitive damages, are not available under the UCL is clear evidence that deterrence by means of monetary penalties is not the act's sole objective. A court cannot, under the equitable powers of section 17203, award whatever form of monetary relief it believes might deter unfair practices. The fact that the "restore" prong of section 17203 is the only reference to monetary penalties in this section indicates that the Legislature intended to limit the available monetary remedies under the act.

There is no case cited by plaintiff where the consumer was entitled in restitution to more than the benefit to defendant. The recent case of *Korea Supply* emphasized that the common law understanding of restitution applies to Business and Professions Code section 17200. The issue in *Korea Supply* is different from this case because *Korea Supply* did not deal with the measurement of restitution per se. The court dealt with the issue of whether disgorgement was a proper remedy for an individual action, not a class action.

The court found that limiting the remedy to restitution was consistent with the policies behind the UCL to prevent practices that constitute unfair competition and to restore to any person in interest money or property acquired as a result of those practices. The court found no case that approved of nonrestitutionary disgorgement of profits as a remedy under the UCL and clarified the semantic confusion in these terms: "While prior cases discussing the UCL may have characterized some of the relief available as 'disgorgement', we were referring to the restitutionary form of disgorgement and not to the nonrestitutionary type."

*25 Though limiting its holding to individual actions,

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the reasoning of the case suggests a broader holding that in any case under the UCL, nonrestitutionary disgorgement is unavailable. The Court implies that the only remedy available is restitution in the traditional sense. Restitution in the common law sense implies restoring only that which the defendant gained in the transaction.

Other cases cited by plaintiff do not challenge this proposition. At least two cases relied upon are inapposite because they affirm civil penalties in favor of the state (*People v. Cappuccio* (1988) 204 Cal.App.3d 750; *People v. Morse* (1993) 21 Cal.App.4th 259). In these cases, restitution was not even an issue.

The case *People ex rel. Bill Lockyer v. Fremont Life Insurance Company* (2003) 104 Cal.App.4th 508, 532 also dealt with a civil penalty. However, the court also evaluated the restitution order under Business and Professions Code section 17203. In that case, the court found that an annuity policy was misleading, based in part on its findings that the "premium charge" was "unusual" and "not conspicuously set forth" in the policy or in the sales brochures. In a restitution order, the court ordered defendant to make an offer of restitution to each nonsettling California consumer (or beneficiary under the terms of the policy), to restore the premium charge. Appellant argued that the order did not restore the status quo but altered the "lawful terms of the annuity contract" because the premium charge itself was lawful. The court rejected this assertion, reasoning that while the premium charge was lawful in itself, the annuity policy was misleading as a whole because of the premium charge term. Thus, the court found that the premium charge was unlawful under the UCL. The court found that the restoration of the premium charge thus restored the status quo. This case is not helpful to plaintiff because nothing indicates that defendant had to pay more than what it unlawfully gained (except the civil penalty).

Finally, plaintiff relies on *Rosales v. Citibank, Federal Savings Bank* (N.D.Cal.2001) 133 F.Supp.2d 1177. In *Rosales*, the plaintiff claimed that he lost money from his bank account due to an unauthorized withdrawal by someone else. Citibank argued that they did not have to restore anything to plaintiff because Citibank did not take anything from plaintiff. However, Citibank did not reimburse plaintiff as required by law. The court found that Citibank thus withheld money belonging to plaintiff and this could be "restored" to plaintiff.

In conclusion, either under a theory of restitution or "disgorgement," the plaintiff class is entitled to "all money obtained" by means of the unlawful practice. The money "obtained" here is received by the defendant from the retailers less the amount paid by defendant to the manufacturer. Anything more would constitute an award of damages (i.e., making the plaintiff "whole.")

*26 The testimony of both damage experts is that the defendant received \$16,538,328 from retailers or direct sales. Dr. Kennedy computed the cost of goods at \$4,001,508, leaving a net to defendant of \$12,536,820. (Exhibit 2279.)

There was testimony that the sales to GNC were understated by 25,000 units which would increase the dollars received by approximately \$400,000. There was also testimony that defendant paid rebates of approximately one dollar per bottle to salespeople at GNC and there were other expenses. None of this is documented and the Court is not allowing any of these items. See Evidence Code section 412.

The largest deduction claimed by defendant is the three to five million dollars of advertising that defendant estimates it spent in California. It would be inequitable to allow the defendant to reduce the amount of restitution by the amount spent on the misleading advertisements. Therefore, the Court is exercising its broad equitable power and is not going to allow the restitutionary amount to be reduced by the advertising expenses.

Finally, since the Court has found virtually all of the advertisements to be misleading, in addition to the first three labels, there should be no reduction for "proportionality," assuming there was authority to support a proportionate reduction. The purchasers of Xenadrine RFA-1 were misled throughout the class period and there is no justification to reduce the amount of restitution from the total amount received by defendant of \$12,536,820.

Therefore, defendant is ordered to pay TWELVE MILLION FIVE HUNDRED THIRTY-SIX THOUSAND EIGHT HUNDRED TWENTY and 00/100 DOLLARS (\$12,536,820.00) into a fund to be distributed as ordered by this Court.

C. Injunctive Relief

Defendant argues that since it is no longer selling

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Xenadrine RFA-1 in California, there cannot be any injunctive relief. This argument is not supported by the statute, Business and Professions Code section 17203, which says: "any person who engages, *has engaged*, or proposes to engage in unfair competition" may be enjoined. (Emphasis Added.) See *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.* (1998) 17 Cal.4th 553, 570.

Therefore, Cytodyne, its officers, principals, agents, servants, employees, successors, assigns, and all those in active concert or participation with them are enjoined and restrained from disseminating or causing to be disseminated, through any advertisement, label, commercial or other promotional activity, any advertising claim which includes representations identical or similar to those claims found to be false or misleading, either directly or by necessary implication, whether material or not.

ATTORNEY'S FEES

Plaintiff's counsel may apply for attorney's fees.

PROCEDURE

If a Statement of Decision is requested, the Court will prepare such Statement. This Tentative Decision shall become the Statement of Decision unless within 10 days either party specifies controverted issues or makes proposals not covered by this Tentative Decision. The Court also requests each side to submit proposals on how the restitution fund is to be distributed.

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Mr. WALDEN. Thank you.

Mr. FRANCE. So, if you want to follow up, in terms of assessing what Mr. Chinery says, in view of the fact that I was at the trial and I prosecuted that case, and also observed Mr. Chinery, Mr. Conklin, Dr. Colker who performed these alleged studies on Xenadrine RFA-1, at least one of them, the Peak Wellness, I question highly what Mr. Chinery had to say.

Mr. WALDEN. All right.

Dr. Woosley, is Xenadrine considered a stimulant?

Mr. WOOSLEY. Yes.

Mr. WALDEN. And what is it and what is its purpose as a dietary supplement for weight loss?

Mr. WOOSLEY. Well, it contains ephedra and ephedrine, which is the major stimulant.

Mr. WALDEN. Okay. And as we understand it, there may be other ingredients contained in these ephedra caffeine dietary supplements including the one I just referenced, so that is why I am asking your opinion on this. It is Tyrosine?

Mr. WOOSLEY. Tyrosine.

Mr. WALDEN. Considered a stimulant?

Mr. WOOSLEY. No. It's an amino acid which in high doses might have pharmacologic effect, but not in the doses likely to be used in these products.

Mr. WALDEN. Is L-carnatine considered a stimulant?

Mr. WOOSLEY. Carnatine, no.

Mr. WALDEN. Okay. What is its purpose?

Mr. WOOSLEY. It is argued. People would not agree about its purpose. It is taken by many people to stimulate muscle growth, but there is no scientific evidence that I am aware of, except in carnatine deficiency.

There are inherited disorders where people do not have enough carnatine, but it is very rare.

Mr. WALDEN. What properties does salicine have, that is white oak bark or something?

Mr. WOOSLEY. It is—probably, and I would have to say that whether the product that is put in there is exactly what the pharmacopeia would say is often not the same. But Salicine is thought to be a salicylic acid base. It is like aspirin.

Mr. WALDEN. Can it cause bleeding?

Mr. WOOSLEY. Yes in high doses. In the doses that are there, we do not know.

Most of these products have never been studied scientifically.

Mr. WALDEN. Because some of these say you should not take aspirin with them.

Mr. WOOSLEY. That is theoretically correct. But, again

Mr. WALDEN. Is salicine similar to aspirin in that respect, the way it may interact?

Mr. WOOSLEY. It is chemically similar to aspirin, but frankly we have no idea what those drugs could do in those products because they have never been tested.

Mr. WALDEN. No idea?

Mr. WOOSLEY. No idea.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

In the absence of other members of the minority party, the Chair will recognize the gentlelady from Colorado again for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Vasquez, I would like to summarize your testimony a little. Our information is that during October 1999 you received about 5 adverse event calls per day and sometimes as many as 13 daily.

Consumers called reporting massive heart attacks and strokes. And you took calls where consumers said that their hearts were pounding in their chests right there. You also took calls reporting Metabolife 356 induced cardiac arrhythmia. And also with information indicating that one out of every five adverse event calls you received were for cardiovascular symptoms.

In addition, you received about 10 calls from emergency room physicians and you and other Metabolife nurses faxed the Metabolife 356 ingredient list to emergency room physicians.

During that approximately 2 plus months you worked at Metabolife International you received 5 to 20 calls regarding heart attack complaints associated with using Metabolife 356.

Is that a pretty good summary of your experience at the company?

Mr. VASQUEZ. Correct. Yes.

Ms. DEGETTE. Thank you.

Now, Mr. Vasquez, we were informed that you attended meetings where Metabolife 356 adverse events were discussed. In those meetings you told our staff that you were instructed to be on heightened security alert in case the FDA or DEA were calling. Is that correct?

Mr. VASQUEZ. Correct. Yes.

Ms. DEGETTE. And who were the instructors giving you these warnings to be on heightened alert?

Mr. VASQUEZ. My supervisor, Mr. Daniel Rodriguez.

Ms. DEGETTE. And what did Mr. Rodriguez tell you you were supposed to do if you received calls from the FDA or the DEA?

Mr. VASQUEZ. Well, basically, just to be careful and if they had any questions, transfer the call to the legal team, the legal department of the company.

Ms. DEGETTE. And you also said that you were instructed not to use the term "side effect" on the phone with callers. Is that right?

Mr. VASQUEZ. Correct. That was primarily because according to Mr. Rodriguez, Metabolife 356 is a dietary supplements, that it is not a drug. That is why he—

Ms. DEGETTE. So you were instructed not to say side effects, right?

Mr. VASQUEZ. Correct.

Ms. DEGETTE. Now you were concerned about that directive, were you not?

Mr. VASQUEZ. Yes.

Ms. DEGETTE. And did you express your reservations to the company?

Mr. VASQUEZ. Yes. I told them why is that the case. And he said, well, because the product is a dietary supplements. And I said well—and he told me it is a matter of legal words what to use and what not to use. So that is why I was instructed not to use the words side—

Ms. DEGETTE. And who was it again that instructed you not to use that word?

Mr. VASQUEZ. Mr. Daniel Rodriguez.

Ms. DEGETTE. Thank you.

One last question, Dr. Woosley. Is citrus aurantium a stimulant?

Mr. WOOSLEY. It probably has stimulant properties. It has chemicals in it like adrenaline. And again, these products have not been studied adequately.

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman. And I yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady.

The Chair recognizes himself for 5 minutes.

Dr. Zipes, can an otherwise healthy person die from simply taking an ephedra supplement?

Mr. ZIPES. Mr. Chairman, the answer to that is yes. The adrenaline response if excessive, can make a normal heart create this rhythm called fibrillation that produces sudden death. We know this from many instances. We know this in animal studies.

I can take a normal dog or pig and produce this with an excessive dose of adrenaline. And we know it from the clinical studies as well.

So without any question the answer is yes.

Mr. WOOSLEY. Mr. Chairman, if I may?

Mr. GREENWOOD. Please do.

Mr. WOOSLEY. Can I make one other point? We have heard mention of "massive heart attack" taking adrenaline, taking the ephedra compounds. And we have heard palpitations. In actual fact those are probably linked, because when the lay public speaks of a massive heart attack, it is usually due to this ventricular fibrillation. It is not an actual heart attack, per se, but it is this abnormal heart rhythm that kills approximately 450,000 people in the United States every year. And it is the immediate sudden death, someone dying quite rapidly.

So it is one end of the extreme of the palpitations where they may be symptomatic from irregular heart beats that when it gets so severe, produces fibrillation and sudden death, which is often called a massive heart attack.

Mr. GREENWOOD. That triggers a question in my mind. Under what circumstances of someone dying like that would there necessarily be a coroner's examination and an inquiry that would determine whether, for instance, a product like ephedra was in that person's body? I would think that, it would seem to me that the rules for when you necessarily have an autopsy and coroner's examination do not necessarily apply to people having heart attacks?

Mr. WOOSLEY. That is correct. Only if someone were suspecting a drug like ephedra would you do the appropriate blood tests to try to document how much was in the blood stream.

Mr. GREENWOOD. Someone like myself could get up in the morning, take one or two of these pills, or whatever it is, go to the gym, be doing the usual workout, have a heart attack and not—it would seem to me it would not be necessarily likely that anybody would ever search the contents of my stomach. They just said, oh, he is 52 years old and heart attack.

Mr. WOOSLEY. That is exactly right. And if an autopsy were done in an otherwise normal individual, there would be nothing found in the heart that would indicate that this was, indeed, ephedra induced.

One other point we have not made that needs to be made, and that is the drug ephedra can interact with other drugs that the patient may be—the individual may be taking for appropriate medical reasons. In addition, there may be underlying heart disease in a 52 year old might have underlying coronary disease that might predispose to developing this ventricular fibrillation and sudden death when now having the added stimulus of ephedra.

Mr. GREENWOOD. Thank you.

Let me address a question to you, Ms. Crosse.

Some have said that your report about the Metabolife call records demonstrated that Metabolife 356 is safe when used as directed. Is this true?

Ms. CROSSE. No, we did not take an overall judgment about the safety of Metabolife 356, but we did point out that the reports in the call records contained information that pointed to some serious adverse events that occurred with users of this product. Many of the call records, however, did not contain the necessary information that would allow you to draw a conclusion about an individual user. However, we did see that the consumers of this product were using it, by and large, within the recommended guidelines on the product label. Over 90 percent of those who experienced a serious adverse event used the product within the recommended dose. Over 70 percent used the product within the recommended duration—and those are for those who were having the most serious side effects, the most serious adverse events associated with the product.

For those who were having less serious or potentially serious adverse events, over 90 percent of those users reported that they were within both the dose and duration that was recommended on the product label.

Mr. GREENWOOD. Let me address a question to Ms. Culmo. In your capacity were you ever aware of a company using the results of a study conducted with regard to one product and then trying to misapply to another product?

Ms. CULMO. Yes. In the Texas Department of Health public docket there is one particular study that on at least, I think it is 4 situations, companies used the same report and just whited out the name at the top of the report, typed in their name and submitted it to our docket. So, yes, there is definitely examples of that and proof.

Mr. GREENWOOD. Okay. I thank the panel.

Mr. Bechler, you had a comment that you would like to make.

Mr. BECHLER. Yes, I do.

Mr. Chairman, I would like to thank everybody for their testimony and the professionals that they have here. I would like to thank all of you up there for being here to try to get this situation taken care of.

And I just wanted everybody to know that I hope that Mr. Riggins and my son did not die in vain, and that you all take this into consideration before anybody else dies, that we do something about it now.

Mr. GREENWOOD. Well, you can count on that, sir.

We thank you very much for both Mr. and Mrs. Bechler and you Mr. Riggins, for what we know is an extraordinarily excruciatingly difficult thing to do. We would not bring you here unless we intended to take this very seriously. And as someone has said, I think it might have been Ms. Culmo, that let us not do another investigation, another study and just recycle this thing. We are going to try to get to the end of this story. And the appropriate end of this story very shortly.

We thank you very much.

The Chair notes we have a series of votes that may take another hour plus. The Chair regrets that, but that is the way things work here.

So we are going to thank this panel, excuse this panel. But we would ask that if any of the expert witnesses are able to remain with us, if their travel plans permit, to remain with us because we may want to call upon you again.

But we will return in about an hour to bring forward this second panel. Thank you again.

[Brief recess.]

Mr. GREENWOOD. The meeting will come to order.

The Chair apologizes for what we know is a torturously long pause in our activities, but it is one in which we have no choice.

And I will call forward our second panel, Mr. Michael Ellis, Mr. David Brown and Mr. Daniel Rodriguez. Please come to the witness table, gentlemen.

Michael Ellis is the founder and Director of Metabolife International. David Brown is a former President of Metabolife. And Daniel Rodriguez is the head nurse working at Metabolife handling consumer complaints.

They are all here with us today pursuant to a subpoena.

On July 3, 2003 the committee invited these three individuals to voluntarily testify at this hearing, but they declined.

On July 10 of this year the subcommittee authorized subpoenas to be issued to compel their appearance, which were subsequently issued by Chairman Tauzin and served. My understanding is that these witnesses will rely on their Constitutional right not to testify at today's hearing and will not provide any evidence or testimony to this subcommittee.

I believe that this privilege, which is the only basis upon which a witness may refuse to cooperate with an inquiry by this House, the People's House of Representatives, should be personally exercised before the members as is our standard practice in such cases. That is why we have insisted on the appearances of Mr. Ellis, Mr. Brown and Mr. Rodriguez today.

Given the importance of their testimony to this subcommittee's fact-finding processes, I would hope that these men might reconsider their decisions to invoke their Fifth Amendment rights today and decide to cooperate with this critically important investigation.

Mr. Ellis, Mr. Brown, Mr. Rodriguez, I know that each of you is represented by counsel today who will advise you with respect to your appearance, as is your right under the rules of the House and the rules of the committee.

Mr. Ellis is represented by Andrew Robertson of the law firm LaBella & McNamara.

Mr. Brown is represented by Gordon Greenberg of the law firm McDermott, Will & Emery.

And Mr. Rodriguez is represented by Lee Blalack of the law firm O'Melvaney & Myers.

As such I understand that each of you is aware that the subcommittee is holding an investigation hearing today and in doing so, has the practice of taking testimony under oath. At this time would you please, stand, raise your right hand and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You may please be seated.

The Chair will then recognize himself for questioning of the witnesses.

Oh, I am sorry. You are now under oath and you may give a 5 minute oral statement for the record if you choose to. Does anyone choose to do that? Apparently not.

TESTIMONY OF MICHAEL ELLIS, FOUNDER AND DIRECTOR OF METABOLIFE INTERNATIONAL; DAVID BROWN, FORMER PRESIDENT OF METABOLIFE; AND DANIEL RODRIGUEZ, HEAD NURSE, METABOLIFE

Mr. GREENWOOD. The Chairman then will recognize himself for questioning of the witness. My first question is for Mr. Ellis.

As the one time president of a company selling supplement products ingested by millions of consumers, did Metabolife ever conduct any studies on the risks associated with use of its product Metabolife 356 or did you put sales above safety?

Mr. ELLIS. I respectfully decline.

Mr. GREENWOOD. Would you please push the button your microphone?

Mr. ELLIS. Thank you. I am sorry.

Mr. GREENWOOD. That is quite all right.

Mr. ELLIS. I respectfully decline to answer that question in this proceedings based upon my privilege against self-incrimination, sir.

Mr. GREENWOOD. Okay. Let me be clear. Are you refusing to answer the question on the basis of the protections afforded to you under the Fifth Amendment to the United States Constitution?

Mr. ELLIS. Yes, sir.

Mr. GREENWOOD. And will you invoke your Fifth Amendment rights in response to all of our questions today?

Mr. ELLIS. Yes, sir.

Mr. GREENWOOD. Then you are excused from the witness table at this time. But I advise you that you remain subject to the process of the committee and that if the need is such, then we may recall you.

Mr. ELLIS. Thank you, sir.

Mr. GREENWOOD. You may be excused.

My next question is for Mr. Brown.

Mr. Brown, welcome.

As the one time president of a company selling supplement products ingested by millions of consumers why did it take several years for Metabolife to send into the FDA the 14,000 customer com-

plaint call records, many of them involving serious adverse medical events after years of insisting that Metabolife had received no such complaints.

Mr. BROWN. Mr. Chairman, members of the committee, under normal circumstances I would be happy to be here with the committee and answer all of your questions. Unfortunately, due to an investigation by the Justice Department in California, I think it would be inappropriate for me to answer your questions today. And, therefore, I am going to follow the advice of my attorney and out of prudence decline to answer the committee's questions today based upon my rights under the Fifth Amendment of the Constitution.

Mr. GREENWOOD. Very well said. And that is indeed your right. But let me clear, are you refusing to answer the question on the basis of the protections afforded to you under the Fifth Amendment to the United States Constitution?

Mr. BROWN. Yes, sir.

Mr. GREENWOOD. Okay. And will you invoke your Fifth Amendment rights in response to all of our questions today?

Mr. BROWN. Yes.

Mr. GREENWOOD. Then you are excused from the witness table at this time. But I advise you that you remain subject to the process of the committee and that if the committee's need is such, then we may recall you.

Mr. GREENBERG. Mr. Chairman, one housecleaning matter if I may.

We submitted 4 letters to the committee for its consideration. We would request that those 4 letters be part of the record of today's proceedings, please.

Ms. DEGETTE. Reserving the right to object. We have not seen the letters.

Mr. GREENWOOD. The gentlelady would like to preserve her right. We will provide her with all of the letters, the four letters.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. GREENBERG. Thank you, Mr. Chairman.

Chairman TAUZIN. Mr. Chairman, I will also make an inquiry of the Chair. When a witness refuses to testify under the protection of the Fifth Amendment, is that witness permitted to enter information into the record by way of letter when that witnesses refuses to make personal comments or to answer questions before this committee?

Mr. GREENWOOD. I am advised, Mr. Chairman, that the question is a pertinent one. We will review the letters and we will advise Mr. Brown and his attorney as to our conclusion on that matter.

Chairman TAUZIN. I simply, if the Chair will continue to yield, I simply would like to in the intervening time pose an objection, if that is proper, to the introduction of testimony by way of letters to this committee to witnesses who refuse to give oral testimony and to answer questions before this committee for any purpose. And I would like that objective lodged into the record.

Ms. DEGETTE. If the Chairman will yield?

Chairman TAUZIN. I think——

Mr. GREENWOOD. The Chair will yield to the gentlelady from Colorado.

Ms. DEGETTE. One of the reasons I reserved the right to object is I am not sure that—I have not seen the letters. I have no idea what they say. But if they contain substantive testimony, a witness cannot have it both ways; both asserting their rights to their Fifth Amendment privilege and submitting testimony. And I would submit if these letters contain substantive testimony, the witness may be waiving his right under the Fifth—and subject to further subpoena to come back to this committee and testify under oath.

Mr. STEARNS. Mr. Chairman, can I ask a question?

Mr. GREENWOOD. The gentleman from Florida.

Mr. STEARNS. Mr. Chairman, if we accept the letters, would Mr. Brown be willing to answer questions based upon the contents of that letter?

Mr. GREENBERG. If I may respond, Mr. Chairman?

Mr. GREENWOOD. Please do.

Mr. GREENBERG. The letters contain no substantive testimony. They describe our position as Mr. Brown has presented and the sequence of events in corresponding with the committee asking the committee to take consideration that it would not be worthwhile to have Mr. Brown travel here for this proceedings in light of what we were facing today. And that is the substance of our letters. No substantive testimony whatsoever.

Chairman TAUZIN. Mr. Chairman?

Mr. GREENWOOD. Mr. Chairman.

Chairman TAUZIN. If that is the purpose of the letters, they have no relevance to these proceedings. And I would object to their entry into the record.

Mr. GREENWOOD. The Chair registers the objection and the letters will not be made a part of the record.

And Mr. Brown is dismissed.

The next question is for Mr. Rodriguez.

Mr. Rodriguez, as the supervisor of nurses and company representatives handling customer complaints about the Metabolife product, some of them relating to serious adverse medical events, did you in fact instruct these nurses and representatives not to obtain from these callers critical information about these adverse health effects?

Mr. BLALACK. Mr. Chairman, may I be heard on behalf of Mr. Rodriguez?

Mr. GREENWOOD. You may.

Mr. BLALACK. My name is Lee Blalack, and I am counsel for Mr. Rodriguez. As I have advised the subcommittee in a letter that I distributed to all of the members, including staff, Mr. Rodriguez is a witness cooperating with the Department of Justice investigation in the Southern District of California. He has been interviewed by the Justice Department, has given testimony to a grand jury in that proceeding pursuant to immunity.

Given the fact that he would be testifying today under oath on the very same subject matter about which he is giving cooperative testimony in the grand jury proceeding, we asked the subcommittee to consider a grant of immunity to permit him to testify today. That request was denied, and we submitted to the Chair an affidavit from Mr. Rodriguez attesting that if he was compelled to appear, he would have to assert his Constitutional rights against self-

incrimination under those circumstances. And that if he was compelled to appear, he would not be provide any substantive answers to questions.

Under those circumstances, Mr. Chairman, we think it is appropriate that the subcommittee, as is its right, to test that claim if it sees appropriate, but to do so under its rules in Executive Session under Rule 11(k)(5). Because under those circumstances the testimony would—the purpose of the question would have no meaning except to expose him to ridicule and defaming him in the context of his community at home with the press, quite frankly. And so under Rule 11(k)(5) which states whenever a witness, it is asserted by a witness that the evidence or testimony that the witness would give at a hearing may tend to defame, degrade or incriminate, then such testimony upon a majority vote of the subcommittee may be taken in Executive Session.

And, Mr. Chairman, we would request that that be invoked at this time. And we do not wish to offer any substantive testimony or evidence into the record. We would like to enter into the record transcripts from prior hearings at the House and the Senate in which this procedure has been employed to move into Executive Session for purposes of taking the assertion of the Fifth Amendment privilege of a witness away from the cameras and the media.

Mr. WALDEN. Mr. Chairman, I have a motion at the desk.

Mr. GREENWOOD. The gentleman will suspend.

The witness, Mr. Rodriguez, has invoked Rule 11, clause (2)(k)(5) of the rules of the House of Representatives which provides that whenever it is asserted by a witness that the evidence or testimony the witness would give may tend to defame, degrade or incriminate the witness, the subcommittee must vote as to whether to continue to proceed with receiving such testimony in open session or whether it should go into executive session to hear such testimony.

The Chair now recognizes Mr. Walden for the purpose of offering a motion.

Mr. WALDEN. Mr. Chairman, I have a motion at the desk.

Mr. GREENWOOD. The Clerk will read the motion.

The CLERK. Motion by Mr. Walden. Mr. Walden moves that the testimony of the witness invoking his Fifth Amendment privileges not to testify may not tend to defame, degrade or incriminate such a witness, and that therefore the subcommittee should remain in open session.

Mr. GREENWOOD. The Chair recognizes himself on the motion.

It is the Chair's legal view upon consultation with committee counsel that this rule is inapplicable in situations in which it is clear by the witness' own prehearing communications with the committee that the witness will not provide any evidence or testimony at all, but will instead invoke his Fifth Amendment right not to testify in response to any and all questions posed by the subcommittee.

The witness in this case has claimed through counsel that the very act of asserting his Fifth Amendment rights may tend to defame, degrade or incriminate him. I strongly disagree with this assertion based on the longstanding constitutional rule and the judicial context that no negative inference may be drawn from a witness' assertion of his Fifth Amendment rights.

The Chair would thus urge all members to vote to continue this proceeding in an open session and would recognize any other member at this point for purpose of debate on this question. Any members choose to be recognized? Hearing none, the Chair——

Ms. DEGETTE. Actually, Mr. Chairman?

Mr. GREENWOOD. The gentlelady from Colorado is recognized.

Ms. DEGETTE. Is the purpose of this motion to say that the committee—or maybe I can ask the author of the motion.

Mr. WALDEN. Certainly.

Ms. DEGETTE. Is the purpose to say that it is the committee's position that whenever a witness invokes a Fifth Amendment privilege not to testify, it is our determination that does not defame, degrade or incriminate that witness?

Mr. GREENWOOD. Yes.

Ms. DEGETTE. In that case, Mr. Chairman, I would ask unanimous consent that the word "may" from the second line be changed to "does." I do not think the motion is grammatically correct as written.

Mr. WALDEN. I will leave it to the grammarians as long as it accomplishes the same thing. I have no problem with that.

Mr. STEARNS. Mr. Chairman, I like the word "may" better. I think it is appropriate. I think the staff did a better job with the word "may."

Ms. DEGETTE. Staff's agreeing it should be "does."

Mr. STEARNS. The staff thinks it should be "does"?

Ms. DEGETTE. Yes.

Mr. GREENWOOD. The Chair would propose——

Chairman TAUZIN. Mr. Chairman, if I could?

Mr. GREENWOOD. Does the gentlelady withdraw her suggestion? The Chair would ask that she would, insofar as counsel has——

Ms. DEGETTE. I will withdraw it, but I think it is grammatically incorrect.

Mr. WALDEN. Mr. Chairman? Mr. Chairman, my understanding is this wording tracks exactly what is in the House rules.

Mr. GREENWOOD. The gentlelady insists upon her wisdom, but agrees to withdraw her objection.

Ms. DEGETTE. That is better.

Mr. GREENWOOD. Okay. Hearing no further debate, we will put the question on the motion. All in favor say aye.

[Vote]

Mr. GREENWOOD. All opposed no. The Clerk will call the roll?

The CLERK. Mr. Bilirakis?

[No response]

The CLERK. Mr. Sterns.

Mr. STEARNS. Aye.

The CLERK. Mr. Sterns votes aye.

Mr. Burr?

[No response]

The CLERK. Mr. Bass?

Mr. BASS. Aye.

The CLERK. Mr. Bass votes aye.

Mr. Walden?

Mr. WALDEN. Aye.

The CLERK. Mr. Walden votes aye.

Mr. Ferguson?

[No response.]

The CLERK. Mr. Rogers?

[No response.]

The CLERK. Mr. Tauzin?

Chairman TAUZIN. Aye.

The CLERK. Mr. Tauzin votes aye.

Mr. Deutsch?

[No response.]

The CLERK. Ms. DeGette?

Ms. DEGETTE. Aye.

The CLERK. Ms. DeGette votes aye.

Mr. Davis.

Mr. DAVIS. Aye.

The CLERK. Mr. Davis vote aye.

Ms. Schakowsky?

Ms. SCHAKOWSKY. Aye.

The CLERK. Ms. Schakowsky votes aye.

Mr. Waxman?

Mr. WAXMAN. Aye.

The CLERK. Mr. Waxman votes aye.

Mr. Rush?

[No response.]

The CLERK. Mr. Dingell?

[No response.]

The CLERK. Mr. Greenwood.

Mr. GREENWOOD. Aye.

The CLERK. Mr. Greenwood votes aye.

Mr. GREENWOOD. The Clerk will report the roll.

The CLERK. Mr. Chairman, there are 8 ayes, no nays.

Mr. GREENWOOD. The motion carries. The subcommittee will continue to proceed in open session, and I will renew my question to Mr. Rodriguez.

Mr. Rodriguez, as the supervisor of nurses and company representatives handling customer complaints about the Metabolife product, some of them relating to serious adverse medical events did you in fact instruct these nurses and representatives not to obtain from these callers critical information about these adverse health events?

Mr. RODRIGUEZ. Mr. Chairman and members of the committee, on advice of counsel I do respectfully submit my rights under the Fifth Amendment to not testify.

Mr. GREENWOOD. That is your right. Let me clear now, Mr. Rodriguez. Are you refusing to answer the question on the basis of the protections afforded to you under the Fifth Amendment to the United States Constitution?

Mr. RODRIGUEZ. Yes, Mr. Chairman.

Mr. GREENWOOD. Okay. And will you invoke your Fifth Amendment rights in response to all of our questions here today?

Mr. RODRIGUEZ. Yes, Mr. Chairman.

Mr. GREENWOOD. Then you are excused from the witness table at this time, but I advise you that you remain subject to the process of the committee and that if the committee's need is such, then we may recall you.

Mr. BLALACK. Mr. Chairman, will the request that I made that the transcripts from the other hearings be entered into the record, will that be granted or denied?

Mr. GREENWOOD. The gentleman is advised that you may submit your documents to counsel. We will review them, but they will not be inserted into the record.

Mr. BLALACK. Okay. Thank you.

Mr. GREENWOOD. The Chair thanks from the gentleman.

And the Chair now calls forward the patient panel III witness. Mr. Russell Schreck, Chief Executive Officer of Metabolife International; Mr. Robert Hermann, Vice President Metabolife International, Dr. Carol Boozer, Obesity Research Center, St. Luke's Roosevelt Hospital in New York; Mr. Robert Chinery, President of Cytodyne Technologies; Mr. Kelly Conklin of Cytodyne Technologies; Dr. Carlon M. Colker, M.D., Chief Executive Officer and Medical Director of Peak Wellness, Inc. in Greenwich, Connecticut; Mr. Robert Occhifinto, President of NVE Pharmaceuticals, and; Ms. Roseann Fox, Customer Service Representative of NVE Pharmaceuticals.

We welcome all of our witnesses. Again, we do thank you for your patience. We know this has been a long day and we will try to move expeditiously from this point forward.

I believe that you have been advised, and if not I will advise you, that this is an investigative hearing and it is the practice of this subcommittee to take testimony under oath. Do any of you object to giving your testimony under oath today? Seeing no such objection, I would also advise you that pursuant to the rules of this committee and pursuant to the rules of the House, that you are entitled to be represented by counsel. Do any of you wish to be represented by counsel today?

Okay. Let's start with Mr. Schreck. Do you?

Mr. SCHRECK. Yes, I am.

Mr. GREENWOOD. Would you advise the committee of the name of your counsel?

Mr. SCHRECK. Lee Blalack.

Mr. GREENWOOD. Okay. Mr. Blalack.

Mr. Hermann, your counsel?

Mr. HERMANN. Yes, Mr. Chairman. Lee Blalack.

Mr. GREENWOOD. The same gentleman?

Mr. HERMANN. Yes, sir.

Mr. GREENWOOD. Dr. Boozer?

You'll each have to push the buttons on your mike. Okay. Try that. That's much better.

Dr. BOOZER. Mr. Chairman, I have with me today Mr. James Hamilton and Ms. Pamela Davis.

Mr. GREENWOOD. Very well.

And do you gentleman or lady wish to be represented by counsel today? Okay.

In that case, I would ask if you would all—oaky. I'm sorry. Mr. Chinery, do you have counsel?

Mr. CHINERY. Yes, Mr. Chairman.

Mr. GREENWOOD. Would you identify your counsel please?

Mr. CHINERY. Hunter Carter and Shane Friedman.

Mr. GREENWOOD. Very well. Okay.

And Mr. Conklin, you do as well?

Mr. CONKLIN. Yes, sir. It is Steve Kenilman and Shane Friedman.

Mr. GREENWOOD. Very well.

Mr. Colker?

Mr. COLKER. John Wickman and Hunter Carter.

Mr. GREENWOOD. Mr. Occhifinto?

Mr. OCCHIFINTO. William Teller.

Mr. GREENWOOD. And Ms. Fox?

Ms. FOX. William Teller.

Mr. GREENWOOD. Very well. Okay.

Now I would ask if you would please stand and raise your right hands.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are all under oath and we will begin with Mr. Schreck, you are invited to offer your testimony, sir. And you need to make sure your microphone is on.

TESTIMONY OF RUSSELL SCHRECK, CHIEF EXECUTIVE OFFICER, METABOLIFE INTERNATIONAL; ROBERT HERMANN, VICE PRESIDENT METABOLIFE INTERNATIONAL; CAROL BOOZER, OBESITY RESEARCH CENTER, ST. LUKE'S ROOSEVELT HOSPITAL; ROBERT CHINERY, PRESIDENT, CYTODYNE TECHNOLOGIES; KELLY CONKLIN, CYTODYNE TECHNOLOGIES; CARLON M. COLKER, CHIEF EXECUTIVE OFFICER AND MEDICAL DIRECTOR, PEAK WELLNESS, INC.; ROBERT OCCHIFINTO, PRESIDENT, NVE PHARMACEUTICALS; AND ROSEANN FOX, CUSTOMER SERVICE REPRESENTATIVE, NVE PHARMACEUTICALS

Mr. SCHRECK. Chairman Greenwood and members of the subcommittee, my name is Russell Schreck. And I am the President and Chief Executive Officer of Metabolife International.

Metabolife is one of the leading companies in the dietary supplement industry. It is my privilege to appear before the subcommittee today to discuss the many important issues of consumer choice and health that pertain to our industry.

At the outset, Mr. Chairman, I should note for the record that I have been with the company for a very short time and may need to rely on my colleague for certain instances.

I am proud to be a part of Metabolife. I know that one of the most important things that have occurred since I have been part of the company is the enormous time and resources its spent to cooperate with the committee.

One of the reasons we have cooperated so extensively with the subcommittee is that we hope that your inquiry would dispel some of the public confusion surrounding dietary supplements containing ephedra. We are, obviously, quite sensitive to the concerns that have been expressed regarding the proper marketing and use of ephedra products, including by the Bechler family and Mr. Riggins this morning. Speaking as a parent for 10 children, I can tell you that myself and Metabolife express our deepest sorrow and sympathy to these families.

Our genuine concern notwithstanding, these events do not shake us from our firm belief in the safety and efficacy of our products.

Our company markets one of the largest weight control—one of the leading weight control supplements, a product called Metabolife 356. It is not for everyone, as we clearly state on our label. The FDA and the NIH recently commissioned a study by the Rand Corporation which found that dietary supplements containing ephedra such as Metabolife 356 are effective at supporting short term weight loss. Moreover, the Rand study noted that no serious adverse events were reported in the 52 clinical trials.

The FDA had previously found that synthetic ephedrine is generally safe and effective at doses of 150 milligrams per day in the over-the-counter drug such as asthma remedies. By comparison, our label on Metabolife 356 establishes a daily serving limit of no more than 96 milligrams per day of ephedrine alkaloids. And because Congress had the foresight to pass the Dietary Supplement, Health and Education Act of 1994, millions of consumers have been able to take advantage of ephedra products to achieve their weight loss goals. We estimate at Metabolife that for the 5 year period ending August 2002 we have sold approximately 50 million bottles of Metabolife 356 containing approximately 4.5 billion tablets.

Mr. Chairman, we take the questions about safety and efficacy of our products very seriously. So even though we believe that our products are safe, our company has a longstanding policy of prohibiting the sale of Metabolife to minors. We do not market Metabolife 356 as an alternative illicit street drug and we have not promoted our product as a means of athletic enhancement.

Anyone who has read our label know that we go to great lengths to inform our customers about the proper use of our products. And, as you can see, the label has been put on the stand in the corner there.

We make it quite clear in our label that ephedra products are not to be sold or used by minors and that customers with preexisting medical conditions should consult a physician before product use.

We also make clear to our customers on that label that exceeding the recommended serving may cause serious adverse health effects, including heart attack and stroke.

Metabolife does not oppose regulation and strongly believes that the FDA should adopt and implement a strong science based regulation that would restrict promotional claims, mandate serving limits and generally require companies to act responsibly when manufacturing and selling their products. I say science based because we know, as you do, Mr. Chairman, that the debaters surrounding ephedra can be very emotional. We do not believe that the FDA should regulate based on anecdotes or emotions, but rather should rely on science.

And as the Rand study noted, no serious adverse effects were reported in the 52 clinical trials.

I hope that industry and policymakers can work together to promote the safe use of a product that millions and millions of Americans find helpful to struggle to maintain their weight.

Thank you, Mr. Chairman. I would be pleased to answer any questions you may have.

Mr. GREENWOOD. Thank you, Mr. Schreck.

Mr. Hermann, you are recognized for your opening statement, sir.

TESTIMONY OF ROBERT HERMANN

Mr. HERMANN. Thank you, Mr. Chairman, for the opportunity to address the subcommittee. My name is Bob Hermann. I am Vice President of Operations for Metabolife. I've been in this position since January 2000 and I have been an employee of Metabolife for about a little over 3½ years.

My primary responsibility is for the company's manufacturing facility and manufacturing process. Day in and day out Metabolife employees in California and Utah work to ensure that our products are both effective and safe. I can personally attest to the rigorous quality control measures that are performed on all of our products, including Metabolife 356. Despite the fact that final rule establishing good manufacturing process for dietary supplements has not been issued yet, Metabolife has voluntarily implemented stringent quality control procedures, including batch-testing, which meet or exceed the FDA's requirement for food GMPs.

As Mr. Schreck has already indicated, Metabolife does not oppose reasonable regulation of the marketing and the use of dietary supplements containing ephedra. In fact, our label makes clear, we already prohibit the sale of Metabolife 356 to minors; we specify maximum serving limit consistent with available clinical evidence; and we utilize blunt warning statement to advise people with pre-existing medical conditions to seek the counsel of a health care professional before using our product. To, to be clear, Metabolife welcomes prudent regulation. We ask only that it's grounded on the rigors of clinical evidence, rather than the hearsay of anecdotal reports.

Mr. Chairman, some of our critics have suggested that anecdotal reports maintained by the FDA and call records kept by Metabolife provide compelling evidence that ephedra poses a safety hazard. We, obviously, disagree. We continue to believe the consumer reports cannot substitute for well-controlled scientific studies. However, you need not take our word for it.

Your own investigators at the General Accounting Office reviewed the so called adverse event reports maintained by the FDA and, in 1999, concluded that the reports were unreliable, inconsistent and incapable of establishing causation. And, just a few months ago, the GAO reported on its analysis of the consumer calls recorded by Metabolife from May 1997 to July 2002. As you know, Mr. Chairman, Metabolife voluntarily produced call records from our health information line for GAO's analysis. The GAO found, and I quote, "We cannot establish that any of the adverse events reported in the Metabolife International call records were caused by the use of Metabolife 356... adverse event reports by themselves are generally not sufficient to establish that a health problem was caused by the use of a particular product."

But for those who reject GAO's analysis and continue to put great stock in these reports, it is imperative to appreciate some essential context about our call record. One of the most important facts to understand is that Metabolife's consumer information line was never intended to be a reporting system for adverse health events. The information line was merely intended to be a means for our customers to ask general questions about the proper use of our products and to assist them in weight loss questions. As a con-

sequences, it should not be surprising that, between 1997 and 2002, only about 3 of every 100 calls pertained to health-related issues. Moreover, based on the GAO's count, only about 6 out of 1,000 of these health-related calls pertained to significant health allegations, such as stroke or heart attack. In other words, a tiny fraction of 1 percent of all recorded calls to the consumer's information line were considered significant.

When these figures are considered and compared to approximately 4.5 billion tablets of Metabolife sold during this same period, one can see why the GAO concluded that anecdotal call records are inadequate to establish a causal link between an adverse health outcome and ephedra-containing dietary supplements.

To appreciate how misleading anecdotal records truly are, I encourage the subcommittee to compare reports about other commonly used products, such as aspirin and acetaminophen, the generic name for Tylenol. For example, in the year 2001 alone, the American Association of Poison Control Centers received thousands of anecdotal reports of health problems associated with aspirin and acetaminophen. In that 1 year, there were more than 17,000 reports to the Poison Control Centers involving aspirin, including over 6,000 reports of health problems and over 66 reports of death. The numbers are even more striking for acetaminophen, 56,000 reports, including 10,000 reports of health problems and over 120 reports of death. Despite these glaring numbers, I think most of us would agree that aspirin and Tylenol are safe when taken as directed.

Of course, these statistics do not provide a causal link between these products and these health outcomes. But these statistics do highlight the folly of attempting to craft a meaningful regulation on what the GAO called "unreliable" evidence. Secretary Tommy Thompson noted this exact point in a letter to the Public Citizen in June of last year when he stated that "the reports alone do not provide a scientific basis for assessing the safety of ephedrine alkaloids or establish a link between the reported adverse events and the ingestion of ephedrine alkaloids." We agree, Mr. Chairman. Clinical trials, not call records from consumers, are the only sound method to evaluate the safety and efficacy of dietary supplements containing ephedra. To my knowledge, there is not a single well-controlled clinical study which demonstrates that ephedra supplements are unsafe when taken as directed.

I am proud of our company and employees. We believe that we offer our customers valuable tools in their efforts for weight control. As a person most directly in charge of manufacturing, I can assure this subcommittee that none of us at Metabolife would ever permit the sale of a product that would did not feel confident about taking ourselves or giving to our families.

Mr. Chairman, I am pleased to be here today and I am prepared to answer your questions.

Mr. GREENWOOD. Thank you, Mr. Hermann.

Dr. Boozer, you are recognized for your opening statement. Please make sure your microphone is on as well.

TESTIMONY OF CAROL BOOZER

Ms. BOOZER. Mr. Chairman, members of committee and Congresswoman Davis Thank you for your invitation to speak to you today. I am Dr. Carol Boozer. My doctorate in science and nutrition is from Harvard University, School of Public Health. I am presently on the faculties of the Institute of Human Nutrition, in the Department of Medicine at Columbia University and at the New York Obesity Research Center at St. Luke's-Roosevelt Hospital.

I currently receive significant research support from the National Institutes of Health grants. My career has been devoted to research in the areas of nutrition and obesity, which unfortunately is currently at epidemic levels, with the intention to prompt public health.

My interest in this issue is through my role as a scientist who is the principle investigator in two of the very few clinical trials of ephedra/cafeine combinations. My position today is to promote the role of science in the policymaking process in general and in this issue in particular.

The sudden death of any individual is tragic to the family and friends and a loss to the country. The effort to reduce the number of these tragedies and promote public health should be the highest priority. Reports of serious adverse events related to the use of ephedra must be taken seriously, and they are useful in pointing to areas that require research. However, they do not constitute scientific proof of an association between ephedra consumption and injury.

Scientists have carefully considered the methodology required to show causality. The "gold standard" method in clinical studies is the randomized, double-blind, placebo-controlled trial.

The two clinical trials of ephedra-containing products that I conducted both used this method to assess the efficacy for weight loss and safety. An expert statistician provided codes to randomize subjects to two groups. Since none of the research staff involved in the study knew the codes, there was no way that they could bias the results by treating one group differently from the other during the study. Only after the study was completed and after the data had been entered into the computer spreadsheets was the code broken by the statistician who analyzed the data. Any differences that were found could thus be attributed to the treatment.

Dr. Heymsfield who testified this morning was a co-author on one study and a co-investigator on the other one. Our papers were transparent with regard to the compounds studied.

Subject selection, numbers and reasons for dropouts. I agree with Dr. Woosley that it would be unethical to have tested individuals who were not healthy. In other words, we tested people whom we could ethically test.

The two studies together included 234 men and women who were overweight, but otherwise healthy. One study continued for 8 weeks, the other for 6 months. In both studies, those receiving the herbal treatment lost more body weight and body fat and had improved blood lipids compared with those receiving who placebo. No individual in either study experienced serious adverse event. In both studies, the herbal groups had increased heart rate and slightly increased blood pressure relative to placebo groups. Heart irreg-

ularities were not increased. Drop-out rates were similar in the two groups in both studies, but in the 8-week study, the reasons given for dropping out of the herbal treatment group included more self-reported side effects, primarily palpitations. In the 6-month study the drop-outs due to side effects were very few and were similar between the two groups. The side effects reported most by subjects in the herbal groups were: dry mouth, insomnia, headache and heartburn.

After the study was completed I discovered a bottle of capsules from the study that had been mislabeled. I therefore personally examined each of the remaining 326 bottles and reported to the Journal and to the FDA my findings along with the statistical analysis showing that low level of error, 1.6 percent, could not significantly alter the results or conclusions of the study.

Studies were both published in the International Journal of Obesity following peer review by experts in the area subsequent to publication. There have been attacks on the studies by the media and others.

The public is not well served by suppression of scientific studies. The validity of scientific study does not depend on agreement of outcome with preconceived expectation. While no study is perfect, these studies were conducted without pressure from the industry for a predetermined outcome, as evidenced by their contractual agreement to publication of results regardless of outcome. The studies were conducted with impartiality that was assured by the randomized, double-blind, placebo-controlled design. As noted, they were subjected to peer-review and published in a reputable scientific journal.

While efficacy of ephedra in promoting weight loss is now established, the safety of herbal ephedra is not proven for different populations or with different usage. More research is required to determine effects in people who are not healthy, who consume ephedra at levels above those studied, or who take it longer than 6 months, or use it in combination with prescription or illicit drugs. But, at present, there is no scientific data proving that consumption of ephedra/cafeine combinations for weight loss are unsafe, when consumed in accordance with appropriate warning labels.

Additional research on the effects of ephedra on weight loss and in other areas, such as athletic performance, is clearly needed. I urge those who are responsible for policy to promote unbiased research and to be guided by its findings.

I'll be happy to answer questions.

[The prepared statement of Carol Boozer follows:]

PREPARED STATEMENT OF CAROL BOOZER

INTRODUCTION

Thank you for the invitation to speak to you today. I am Dr. Carol Boozer. I received my doctorate of science in nutrition from Harvard University, School of Public Health. I am presently on the faculties of the Institute of Human Nutrition, in the Department of Medicine at Columbia University and at the New York Obesity Research Center at St. Luke's-Roosevelt Hospital in New York. I have received research funding from the National Institutes of Health and have served on NIH study sections and as an NIH site visit reviewer. I currently receive significant research support from NIH grants. My career has been devoted to research in the areas of nutrition and obesity with the intention to promote public health.

Issues relating to ephedra are highly controversial. My interest in this issue is through my role as a scientist who was the principal investigator in two of the very few clinical trials of the efficacy for weight loss and safety of herbal ephedra/caffeine combinations. My position today is to promote the role of science in the policy making process in general and in this issue in particular.

The sudden death of any individual is tragic to the family and friends and a loss to the country. The effort to reduce the number of these tragedies and promote public health should be the highest priority. Reports of adverse events related to the use of ephedra must be taken seriously, and they are useful in pointing to areas that require research. They do not constitute scientific proof of an association between ephedra consumption and injury. The reason why such reports cannot prove cause and effect is easily understood by the following example. If a city is considering whether installation of a traffic light has reduced accidents at a dangerous intersection, both the accident rate before the installation, the "background rate" and the rate after installation must be known. However, even if both rates are known, a difference in rates might not be due to the light itself since other factors such as weather, condition of the road, or the opening of a bar in the area could affect the rate. A reduction in the accident rate following installation of the light cannot, in and of itself, prove that the light caused the change.

Methodology

Scientists have carefully considered the methodology required to show causality. The "gold standard" method in clinical studies is the randomized, double-blind, placebo-controlled trial. Randomization is a process whereby individuals are assigned to treatment groups in such a way that the two groups are similar in all other characteristics, except for the treatment under study. This controls for the possibility of even unknown factors affecting one group differently from the other. Double-blinding insures impartiality, since throughout the study neither the participants nor the investigators know the treatment group of any participant. Finally, inclusion of a placebo group allows assessment of the background rate, in a group that is similar in all aspects to the treatment group, except for the treatment under study.

The two clinical trials of ephedra-containing products that I conducted were both randomized, double-blind, placebo-controlled studies undertaken to assess the efficacy for weight loss and safety of herbal/ephedra combinations. A statistician not involved in carrying out the studies provided the randomization codes using a system that would maximize the chance that placebo and treatment groups would on average be similar in characteristics such as age, body weight, gender distribution, income, education, etc. Since none of the research staff involved in the study knew the codes, there was no way that they could bias the results by treating one group differently from the other during the study. Only after the study was completed and after the data had been entered into computer spreadsheets was the code broken by the statistician who analyzed the data. The data for the group receiving the ephedra was then compared with the data for the group receiving placebo. Since the groups were similar at the start of the study and followed the same protocol with the exception of the treatment, herbal ephedra/caffeine or placebo, any differences that were found could be attributed to the treatment.

These two studies were the only clinical trials of ephedra and ephedrine that were given the highest ranking for quality in the recently published Rand Report.¹

Results

The two studies together included 234 men and women who were overweight, but otherwise healthy. Half received herbal ephedra/caffeine and half placebo. One study continued for 8 weeks, the other for 6 months. In both studies, those receiving the herbal treatment lost more body weight and body fat and had improved blood lipids compared with those receiving placebo. No individual in either study experienced a significant adverse event (defined in the scientific community as death, heart attack, stroke, etc.). In both studies, the herbal groups had increased heart rate and slightly increased blood pressure relative to placebo groups. Heart monitors, used in the 6-month study, showed that herbal treatment did not increase heart irregularities. Drop-out rates were similar in the herbal and placebo groups in both studies, but in the 8-week study, the reasons given for dropping out of the herbal treatment group included more self-reported side effects (primarily palpitations). In the 6-month study, the numbers of individuals who dropped out due to

¹Shekelle P, M Hady, Morton SC, et al. Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. Evidence Report/Technology Assessment, Number 76, AHRQ Publication No 03-E022, 2003.

side effects were very low and were similar between the two groups. The side effects reported more frequently by all subjects in the herbal groups compared with placebo groups were: dry mouth, insomnia, headache and heartburn.

Reaction

These studies were published in the *International Journal of Obesity*.^{2,3} Prior to publication, experts in the field critically reviewed each paper and made recommendations to the editor as to the validity of methods, interpretation of results and scientific importance, a process called peer-review. Subsequent to publication, there have been attacks on the studies by the media and others.⁴

The public is not well served by suppression of scientific studies. The value of scientific study does not depend on agreement of outcome with preconceived expectation. While no study is perfect, these studies were conducted without pressure from the industry sponsors for a predetermined outcome, as evidenced by their contractual agreement to publication of results regardless of outcome. The studies were conducted with impartiality that was assured by the randomized, double-blind, placebo-controlled design. They were subjected to peer-review and published in a reputable scientific journal.

Rejection of scientific data in favor of anecdotal stories is inconsistent with the advancement of knowledge or responsible public health policy. The Rand Report reviewed approximately 20,000 adverse event reports.⁵ They classified events as "sentinel" if they provided three things: 1) documentation that the event did occur, 2) documentation or toxicological evidence that the subject had consumed ephedra within 24 hours prior to the adverse event, and 3) evidence that an adequate investigation had assessed and excluded other potential causes. Only 21, approximately 1 in 1,000 reports, reached this level and only two of these were deaths.⁶

One estimate of ephedra consumption in the United States was 12 million people in 1999.⁷ Among such a large number of people, some adverse events would occur whether or not individuals were taking ephedra. Data from the U.S. Government's Division of Vital Statistics estimates the death rate from heart disease alone to be roughly 1 in 5,500 even in young individuals, age 25-44 years.⁸ Among the millions of people consuming ephedra, the background rate of deaths and other serious adverse events would be in the thousands, many fold higher than the 21 documented sentinel events. That is why the Rand Report states that "classification as a sentinel event does not imply a proven cause and effect relationship."⁹

While efficacy of ephedra in promoting weight loss is established, it is not my position that the safety of herbal ephedra is proven for different populations or with different usage. Additional research would be required to determine effects in people who are not healthy, or who consume ephedra at levels above those studied, or for periods longer than six months, or in combination with prescription or illicit drugs. But, at present, there is no scientific data proving that consumption of ephedra/caffeine combinations for weight loss are unsafe, when consumed in accordance with appropriate warning labels.

Additional research on the effects of ephedra on weight loss and in other areas, such as athletic performance, is clearly needed. I urge those who are responsible for policy to promote such research and to be guided by its findings.

Mr. GREENWOOD. Thank you, Dr. Boozer.
Mr. Chinery?

TESTIMONY OF ROBERT CHINERY

Mr. CHINERY. Thank you, Mr. Chairman.

²Boozer, CN, JA Nasser, SB Heymsfield, V Wang, MS Chen and JL Solomon. Efficacy of an herbal mixture of Ma Huang and Guarana for weight loss. *International Journal of Obesity and Related Metabolic Disorders* 25:316-324, 2001.

³Boozer CN, PA Daly, P Homel, JL Solomon, D Blanchard, JA Nasser, R Strauss, T Meredith. Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial. *International Journal of Obesity and Related Metabolic Disorders*, 26:593-604, 2002.

⁴Atkinson, RL. Editorial: The herbal ephedra and caffeine debate continues. *International Journal of Obesity and Related Metabolic Disorders* 26:589, 2002.

⁵See footnote 1.

⁶See footnote 1.

⁷Haller CA, Benowitz NL. Adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids. *New Engl J Med* 343: 1833-1838, 2000.

⁸Minino AM and BL Smith. Deaths: Preliminary Data for 2000. *National Vital Statistics Reports*, Vol 49, Number 12, 2001.

⁹See footnote 1.

My name is Robert Chinery, and I am the former President of Cytodyne Technologies, Inc. I appreciate the opportunity to come before the subcommittee and address the issues surrounding ephedra-based dietary supplements.

The tragic death of baseball pitcher Steve Bechler was the catalyst for this inquiry. Our hearts go out to his wife and new baby, his parents and entire family. Their loss must be difficult to bear. As a husband and a father of 4, I cannot feel anything but sympathy for his family and friends.

I would also like to extend my sympathies to the family of Sean Riggins.

In an effort to understand what happened in this tragedy, we retained one of the top medical examiners in the country to review the autopsy report. Dr. Michael Baden is very well known and highly regarded.

After review of all available records, Dr. Baden determined that Xenadrine RFA-1® did not cause or contribute to Steve Bechler's death. Dr. Baden concluded, specifically, as follows: "I agree with Dr. Perper that the cause of Mr. Bechler's death was heatstroke. However, I disagree as to the cause of this heatstroke. It is my opinion to a reasonable degree of medical certainty that based upon all the materials I have thus far reviewed on my training and on my 43 years experience as a medical examiner that Mr. Bechler died of a heatstroke precipitated by his morbid obesity, high blood pressure and heart disease, adverse weather conditions, physical exertion and inadequate screening, monitoring and medical supervision. The Xenadrine did not cause or contribute to Mr. Bechler's death and that proper and prompt treatment with intravenous fluids and cold wraps immediately after he collapsed but was still conscious may have prevented Mr. Bechler's death."

Numerous other medical experts have made similar public statements. The death of Steve Bechler is the first time ephedra has been blamed as the cause of a fatal heatstroke. But there is no repeat of heatstroke associated with ephedra in the Cantox Report or the Rand Corporation report or in the online medical libraries. In literally dozens of studies, ephedra-based products have been shown to be safe when used properly.

To prevent similar or future tragedies should be the real focus of all of us here. This focus will be lost by improperly seeking to lay the blame on a supplement while ignoring the real factors that may have contributed to the tragedy, such as improper medical screening, training, and treatment by the Baltimore Orioles. It is for these reasons that we have worked so hard to fully cooperate with this investigation.

Cytodyne Technologies worked diligently to market its products responsibly in the firm belief that Xenadrine RFA-1 was safe and effective when used as directed. We took a more conservative approach with our dosage recommendation than doses used in many of the ephedrine/caffeine studies, as well as many of the other products on the market. Our label included very comprehensive warning language and went even beyond recommended industry standards.

We commissioned product specific studies to assess the safety and efficacy of Xenadrine RFA-1. The product studies are not re-

quired of our industry, and many of our competitors, most in fact, have not done them.

Xenadrine RFA-1 is the subject of not one, but 7 independent clinical trials for safety and efficacy. And the results of these studies were accepted for publication and published in the abstract form or full length reports in well respected peer reviewed scientific journals.

We retained and relied upon various experts such as a medical doctor, Ph.D. level nutritional researchers and exercise physiologist as well as other professionals such as regulatory experts who reviewed our labels. We engaged Dr. Carlon Colker, a respected physician as a consultant for medical and academic advice.

In response to a small number of customer complaints beginning in the year 2000 I asked Dr. Colker to work with our company and the customers to learn about such complaints and act as a referral source. Although Congress has not required companies like ours to document or report complaints, we did adopt the policy and practice to record and preserve that information.

Our policy was to tell any customers concerned about adverse effects to stop taking our product and seek medical advice. And we offered the services of Dr. Colker as a referral source.

We have always listened closely to customer feedback, both negative and positive. The customer reports are well known to be unreliable for scientific reasons. Over almost 5 years we sold over 20 million bottles, but received only about 450 complaints. The great majority of these complaints were for mild transient side effects. We never had any reason to believe that Xenadrine RFA-1 caused anything but mild transitory effects.

The available science confirms that ephedra is effective and safe when properly used by healthy individuals. A major report by Cantox Health Sciences International on the safety of ephedra based products contained a comprehensive risk assessment. The Cantox report conducted a thorough review of the available study literature and established that ephedra is safe when used properly according to industry recommendations.

Based on emerging new research, Cytodyne introduced a new formulation which did not contain ephedra just over 1 year ago. And at that time the decision was made to begin phasing our ephedra product and to focus our efforts on the new formulation, which we believe to be superior in efficacy. With the discontinuation of Xenadrine RFA-1 earlier this year, the final phaseout was completed as planned.

Let me state emphatically that our reasons for discontinuing Xenadrine RFA-1 were not in any way based on concerns regarding the safety or efficacy of the product. To the contrary, it is our continued belief that the science supports the position that Xenadrine RFA-1 is safe and effective when used as directed.

The truth is that a ephedra supplements have been used by tens of millions of people in recent years. Unfortunately, with a population this large there is an expected number of medical problems that will always occur whether people use ephedra or not. It is not appropriate to simply blame ephedra every time someone in that population experiences a problem.

The debate over ephedra has become a circus and to decide the future of dietary supplements in a media frenzy would be irresponsible. We are relieved that Congress is stepping in and we are confident that the appropriate responsible steps will now be taken to resolve the issue of the safety of ephedra.

As this subcommittee continues its investigation, I hope that the massive amount of information we have already provided to you and your staff will be helpful. And I look forward to answering your questions.

Thank you.

[The prepared statement of Robert Chinery follows:]

PREPARED STATEMENT OF ROBERT CHINERY, JR., PRESIDENT, NUTRAQUEST INC.

My name is Robert Chinery, Jr., and I am the President of Nutraquest, Inc., formerly known as Cytodyne Technologies, Inc. I appreciate the opportunity to come before the Subcommittee and address the issues surrounding ephedra-based dietary supplements.

I have come here today to cooperate fully, as we have done throughout the investigation by this Subcommittee, even though we are no longer selling an ephedra-based product and are no longer marketing any of the Cytodyne dietary supplements.

Our decision to phase out our ephedra product was a business decision fueled by consumer demand for new and better products, skyrocketing insurance premiums, as well as unjustified media hype regarding ephedra. We developed, and launched in early 2002 a new—and we think better—ephedra-free product, named Xenadrine EFX[®]. That product met with a very positive response from consumers, and quickly surpassed the ephedra-based Xenadrine RFA-1[®], further reinforcing our decision to move in this direction. As a result of the overwhelming positive feedback from consumers, combined with the growing anti-ephedra climate, we believed it would be better to focus on Xenadrine EFX[®]. We began phasing out our ephedra product, Xenadrine RFA-1[®], by ceasing advertising and promotion of it in early 2002. Pursuant to this planned phase-out, we completely stopped selling it in early 2003. Let me state emphatically that we did not discontinue the Xenadrine RFA-1[®] product because we thought there was any merit to concerns regarding the safety or efficacy of the product. To the contrary, it is our continued belief that the science supports the position that Xenadrine RFA-1[®] is safe and effective when used as directed.

Cytodyne Technologies has recently transferred to another leading dietary supplement company all marketing and distribution rights for Cytodyne Technologies products, except Xenadrine RFA-1[®], which was discontinued.

Although we stopped selling the ephedra-based Xenadrine RFA-1[®], we fully cooperated with this investigation because I believe as a citizen, a businessman, a husband and father, that the Congress and the American public should get the facts in the investigation into ephedra-based dietary supplements.

In fully cooperating with the investigation, I have come here voluntarily today, without subpoena, and have instructed our lawyers since day one in this investigation to be as helpful as possible with the Subcommittee and its staff. At great cost, we served eleven responses and supplemental responses, produced thousands and thousands of pages of documents, compiled data and answers for your counsel, and came to Washington for two solid days of interviews of three witnesses. And we have thousands or tens of thousands of pages of documents from satisfied consumers, which we made available to the Committee for its inspection, and we hope you will also consider. The Subcommittee's requests have compelled us, and others, to come forward, and we have accepted that responsibility.

The tragic death of baseball pitcher Steve Bechler was the catalyst for this inquiry. Our hearts go out to his wife and new baby, his parents, and entire family. Their loss must be difficult to bear. He was a very young man and struggling hard to make his place on a major league baseball team. He was an expectant father and was newly married. As a father of four, I cannot feel anything but sympathy for his family. My family and I, and all the people associated and affiliated with Cytodyne Technologies, express our most sincere condolences to Steve Bechler's family and friends.

In an effort to understand what happened in this tragedy, we retained one of the top medical examiners in the country to review the autopsy report. Dr. Michael Baden's sworn opinion is submitted to the Subcommittee as a part of this statement.

Dr. Baden is very well-known and highly regarded. Dr. Baden examined the available information and determined that Xenadrine RFA-1® did not cause or contribute to Steve Bechler's death. Dr. Baden concluded, specifically, as follows:

I agree with Dr. Perper that the cause of Mr. Bechler's death was heat stroke. However, I disagree as to the cause of this heat stroke. Mr. Bechler's poor health, vigorous exercise in hot, muggy weather, severe obesity, abnormal fatty liver, untreated high blood pressure, and enlarged heart are competent factors in and of themselves to be causes of heat stroke. The coincidental toxicologic finding of ephedrine, which is not known to produce heat stroke, in my opinion should not have been linked to the death by the medical examiner—just as the medical examiner did not link the finding of increased level of DHEA to his death.

It is my opinion, to a reasonable degree of medical certainty, based on all of the materials I have thus far reviewed, on my training and on my 43 years experience as a medical examiner, that Mr. Bechler died of a heat stroke precipitated by his morbid obesity, high blood pressure and heart disease, adverse weather conditions, physical exertion, and inadequate screening, monitoring and medical supervision; that Xenadrine did not cause or contribute to Mr. Bechler's death; and that proper and prompter treatment with intravenous fluids and cold wraps immediately after he collapsed but was still conscious may have prevented Mr. Bechler's death.

It should be highlighted that the death of Steve Bechler is the first time ephedra has been blamed as the cause of a fatal heat stroke. There is no report of heat stroke associated with ephedra in the Cantox Report or the RAND Corporation report or found in the online medical libraries. In literally dozens of studies, ephedra-based products have been shown to be safe when used properly.

To prevent future or similar type tragedies should be the real focus of all of us here. This focus will be lost by improperly seeking to lay the blame on a supplement or an industry while ignoring the real factors that caused or contributed to the tragedy, such as improper medical screening, training, and treatment by the Baltimore Orioles. It is our hope that when the true factors come to light proving ephedrine was not the cause of Mr. Bechler's death, that appropriate and reasonable measures will be taken to prevent tragedies like this in the future.

I take the subject of dietary supplements very seriously. I became involved in the supplement industry because I have used the products myself and have experienced their benefits firsthand. After seeing the benefits, it became my passion. I have personally taken ephedra and caffeine products, including our Xenadrine RFA-1®, and it was effective for me. My wife, our family, and many of our friends have also taken and enjoyed the benefits of Xenadrine RFA-1®. Over time, our product became one of the most successful in the dietary supplement industry. Our company has received inspiring feedback from tens of thousands of people who have lost weight and have improved their quality of life using Xenadrine RFA-1®.

In the early 1990's, I worked for a company that sold an ephedra-caffeine product. I was encouraged as I listened to our customers, who were struggling to lose weight and found the ephedra-caffeine combination products very helpful. Weight loss is difficult. America's weight problems are steadily getting worse.

The Centers for Disease Control has posted on its website some very powerful statistics that show Americans are increasingly overweight. As of the year 2000, the prevalence of obesity among U.S. adults was 19.8 percent, which is a 61 percent increase since 1991. In 2000, 38.8 million American adults could be classified as obese, defined as having a Body Mass Index, or BMI, of 30 or more. Between 2000 and 2001, obesity climbed from 19.8 percent of American adults to 20.9 percent of American adults. Currently, more than 44 million Americans are considered obese according to the BMI index; that is, they have a BMI greater than or equal to 30. This reflects an increase of 74 percent since 1991.

Fighting this struggle is emotionally difficult for many people. When something works, it makes a meaningful difference in their lives. That is why, after the first supplement company I worked for was sold, I researched many different dietary supplements and reviewed scientific literature preparing to market a new weight loss product that provided meaningful benefits. Based on the volumes of existing research supporting its safety and efficacy, it seemed clear that a product centered around the ephedrine-caffeine combination offered the best potential.

Those numerous clinical studies showed what we still know today, that the ephedrine-caffeine combination is one of the few combinations that help people lose weight.

Cytodyne Technologies started out as and remains a small business. We had until recently ten employees. The good men and women of Cytodyne Technologies involved in marketing Cytodyne Technologies' products did so responsibly, in the firm

belief that Xenadrine RFA-1® was safe and effective when used as directed. We took seriously the scientific and other information we learned as we marketed Xenadrine RFA-1®, and relied as appropriate on experts and scientific studies. To develop and make Xenadrine RFA-1®, we hired a very reputable manufacturer, run by an experienced pharmacist, that has manufactured hundreds of other nutritional supplements. I was personally familiar with this manufacturer and their expertise from my experience working in the dietary supplement industry. Their products were well-regarded. We felt that this company stood out because they were licensed to make over-the-counter drugs, followed good manufacturing practices, and had a higher level of attention to quality control and a higher quality of product overall.

Although we relied initially on the clinical studies of the ingredients ephedrine and caffeine, we took a more conservative approach than utilized in those studies by implementing a substantially lower dosage of ephedrine and caffeine than what was used and shown to be safe in those studies. Our label included the most comprehensive warning language and went even beyond industry standards. It warned customers to consult a physician before using if they were at risk for certain specific conditions.

We commissioned product-specific studies in marketing our product. Product-specific studies are not required of our industry and many of our competitors—most have not done them. We took that step, though, a total of seven times. We think we helped start a trend in the right direction and our tests demonstrate our efforts to be responsible. These were independent, product-specific, double-blind, randomized, and placebo-controlled (or, in one case, compared to a prescription product). The results were accepted for publication and published in abstract form or full-length reports in well respected, peer-reviewed scientific journals such as the *International Journal of Obesity*. In each study, Xenadrine was shown by statistically significant data to be effective for weight or fat loss within the confines of the study. These studies were also designed to measure certain specific safety criteria, such as vital signs, blood chemistry, blood pressure and EKGs. submissions be made a part of this record.

We retained and relied on various experts, such as a medical doctor, Ph. D.-level nutritional researchers and exercise physiologists, as well as other professionals, such as regulatory counsel who reviewed our labels. We engaged Dr. Carlon Colker, a respected physician, as a consultant after his firm, Peak Wellness, completed the first scientific study on Xenadrine RFA-1®. We wanted someone with his high level of knowledge and background as a consultant. He provided guidance on a number of technical issues, and kept us advised of developments in research and in the dietary supplement industry.

When we received our first complaint alleging a serious adverse health effect, in June of 2000, I asked Dr. Colker to work with our company and the customers to learn about such complaints and act as a referral source so that we could better understand the information. We believe we are the only company that used a medical doctor in this way.

Many stories in the press have focused on customer complaints, as opposed to scientific studies, to allege that ephedra causes serious adverse effects. Although Congress has not required companies like ours to document or report complaints, we did adopt a policy and practice to record and preserve that information. We had a policy and practice in place that any customer complaint of an adverse health effect was directed to Mr. Conklin, who reported directly to me. Our policy was to tell any customer concerned about adverse effects to stop taking our product and seek medical advice, and we offered the services of Dr. Colker as a referral source. We distinguished ourselves from many other companies by having this system.

When asked by the Food and Drug Administration to respond to Adverse Event Reports, we asked Dr. Colker to help us prepare the responses. Dr. Colker gave us his assessment of information he received about customers who called him with medical complaints, and he did not conclude that Xenadrine caused any serious adverse health effects.

Cytodyne Technologies was advised and believes that the complaints are anecdotal and do not indicate that Xenadrine RFA-1® was unsafe, or caused any serious adverse effects for several reasons. Customer reports are well-known to be unreliable for scientific reasons. The General Accounting Office has issued two reports, one in July 1999 and one earlier this year, concluding that adverse event reports and customer call records do not prove cause and effect. Over almost five years, we received a very small number of complaints compared to the volume of our sales. We sold over twenty million bottles—over a billion servings—but we received only about 450 complaints, including many during the recent months of great media attention. The great majority of those complaints were for transient, mild side effects.

We always took customer complaints seriously. Since I started this company, I have listened closely to customer feedback, both negative and positive. We never had any reason to believe that Xenadrine RFA-1® caused anything but mild, transitory effects. We believed this because we relied upon professionals and studies.

During the time we were selling Xenadrine RFA-1®, we did not become aware of any reliable scientific studies finding that there were safety problems with ephedra products. Rumors, news stories, and unscientific information began to circulate with greater frequency, but we did not find that kind of information reliable, nor did our medical consultants.

Instead, the available science confirms that ephedra is effective and safe when properly used. A major report by Cantox Health Sciences International on the safety of ephedra-based products contained a comprehensive risk assessment. The Cantox report conducted a thorough review of the available study literature and established that ephedra is safe when used properly according to industry recommendations. The recent RAND Corporation report also confirms that ephedra works for mild to moderate weight loss. The RAND Corporation concluded (like the General Accounting Office did) that adverse event reports are not reliable to support any conclusions about effects caused by dietary supplements. The RAND Corporation report concluded that there is insufficient evidence to conclude that ephedra poses an imminent health hazard and that further studies need to be conducted.

In comparison to the complaints relating to adverse effects, we received thousands and thousands more responses from satisfied customers praising the benefits of Xenadrine RFA-1®. We sent out and received back tens of thousands of customer satisfaction survey forms, and only a tiny number of them mentioned any dissatisfaction or adverse effects.

We also welcome a chance to respond publicly to news about a recent ruling in a class action lawsuit against us in California. We were surprised and dismayed by the California state court's decision because the judge in that case disregarded the rulings of a federal judge in Utah in 2000, who found the same advertising claims challenged in California were true and not misleading. That federal judge conducted days of hearings and heard the evidence. He approved the reliability and competence of Dr. Colker's clinical study on Xenadrine RFA-1®. Naturally, we relied upon that decision in believing that our advertising was legal, true and not misleading.

Another major error, we believe, in the California case was the total lack of any evidence that the public was misled. There was no evidence concerning what consumers took away from our ads, nor that consumers were misled. It is our position that the judge substituted his personal opinion for hard evidence. We believed, and a federal judge ruled in our favor, that our advertising claims were true and not misleading. We will appeal this decision and we are confident that it will be reversed.

We are just as hopeful that this Subcommittee will fairly consider the information we have presented and be guided by the reliable scientific information and not be caught up in the media hype.

The truth is that ephedra supplements have been used by tens of millions of people in recent years. Unfortunately, with a population this large, there is an expected number of medical problems that will always occur whether those people used ephedra or not. It is not appropriate simply to blame ephedra every time someone in that population experiences a problem. It is unfair, unscientific, unreliable and is an injustice to the right of the American people to make their own choices. The debate over ephedra has become a circus, and to decide the future of dietary supplements in a media frenzy would be irresponsible. We are relieved that Congress is stepping in and we are confident that the appropriate responsible steps will now be taken to resolve the issue of the safety of ephedra.

As this Subcommittee continues its investigation, I hope that the massive amount of information we have already provided to you and your staff will be helpful, and I look forward to answering your questions.

Mr. GREENWOOD. I thank you, Mr. Chinery.

The Chair would advise the members of the committee, the witnesses and the audience that we do have a vote in progress. Unlike the last time we left you and did not return for 2½ hours, we will recess now. We should be back in about 15 minutes.

[Brief recess.]

Mr. GREENWOOD. Mr. Conklin, I believe that you are next. And you are recognized to give your opening statement. And make sure that microphone is facing you and turned on, please.

TESTIMONY OF KELLY CONKLIN

Mr. CONKLIN. Thank you, Mr. Chairman.

My name is Kelly Conklin, I am a consultant to Cytodyne LLC and, until very recently, I worked for Cytodyne Technologies, Inc., which is now known as Nutraquest, Inc. Cytodyne LLC recently acquired the rights to market Cytodyne Technologies' products, except for Xenadrine RFA-1[®], the ephedra-based dietary supplement, which was discontinued as of February this year. Although we did not have very formal titles, I served as the Director of Public and Customer Relations for Cytodyne Technologies, Inc. I began working part-time for Cytodyne Technologies in 1997, while I was still employed as a Police Officer for the Dover Township, New Jersey, Police Department. I graduated from the New Jersey State Police Academy first in my class in the academic and physical components.

While I worked at Cytodyne Technologies, one of my responsibilities was to deal with customers who contacted us with concerns about possible adverse effects that they experienced while taking Xenadrine RFA-1[®]. Beginning sometime in early 2000, Cytodyne Technologies received such complaints and Mr. Chinery, the owner of Cytodyne, asked me to take responsibility for handling the complaints. We received very few complaints initially. When, in June 2000, we received our first complaint of a potentially serious adverse effect, Mr. Chinery arranged for us to be able to refer such customers to Dr. Carlon Colker, and for Dr. Colker to review that complaint and provide us with any guidance or information that we needed.

We tried to continue to improve over time the way we took information from callers. Many consumer calls or correspondence were not specific enough for us to determine whether Xenadrine RFA-1[®] was even used, to document the effect reported, or to ascertain information about other possible causes. Sometimes, the consumer indicated improper use of the product, pre-existing conditions that they thought might account for the reported event, or other information indicating that the connection to Xenadrine RFA-1[®] may be missing.

Since we at Cytodyne were not medically trained, however, we engaged Dr. Carlon Colker to help us understand and deal with customer complaints of alleged adverse effects. By engaging a medical doctor to guide us in this regard, we felt we were being very responsible. In addition, Dr. Colker provided responses for Cytodyne Technologies concerning adverse event report forms forwarded to Cytodyne Technologies by the Food and Drug Administration. According to our records, the company has received complaints of adverse effects from the use of Xenadrine RFA-1[®] over a several year period during which approximately 20 million bottles of the product were sold, each containing 120 capsules, for a total of about 1.2 billion servings. After an extensive review by the company and its attorneys, our records indicate a total of just under 450 customers contacted Cytodyne Technologies concerning

their complaints about the use of Xenadrine RFA-1[®], and most of those were for mild, transitory effects.

It was our policy and practice to advise customers that if they were experiencing adverse effects, they should discontinue the use of the product, and contact their physician. We made Dr. Colker available to them to learn more about their situation and perhaps share some information with them concerning Xenadrine RFA-1. Dr. Colker also advised us of the inherently unreliable nature of adverse event reports and customer complaints, and that many scientific studies showed ephedra-based dietary supplements to be effective and safe within the confines of the clinical studies and when used appropriately. Nevertheless, we paid attention to the information reported to him and reported from him to us, which we have of course turned over to the committee in full.

I am prepared to try to answer any questions and provide this information to Congress and the American public.

Thank you, Mr. Chairman.

[The prepared statement of Kelly Conklin follows:]

PREPARED STATEMENT OF KELLY CONKLIN, CYTODYNE LLC

My name is Kelly Conklin, I am a consultant to Cytodyne LLC and, until very recently, I worked for Cytodyne Technologies, Inc., which is now known as Nutraquest, Inc. (Cytodyne LLC recently acquired the rights to market Cytodyne Technologies' products, except Xenadrine RFA-1[®], the ephedra-based dietary supplement, which was discontinued as of February this year.) Although we did not have very formal titles, I served as the Director of Public and Customer Relations for Cytodyne Technologies, Inc. I began working part-time for Cytodyne Technologies in 1997, while I was still employed as a Police Officer for the Dover Township, New Jersey, Police Department. I graduated from the New Jersey State Police Academy first in my class in the academic and physical components.

While I worked at Cytodyne Technologies, one of my responsibilities was to deal with customers who contacted us with concerns about possible adverse effects that they experienced while taking Xenadrine RFA-1[®]. Beginning sometime in early 2000, Cytodyne Technologies received such complaints and Mr. Chinery, the owner of Cytodyne Technologies, asked me to take responsibility for handling the complaints. We received very few complaints initially. When, in June 2000, we received our first complaint of a potentially serious adverse effect, Mr. Chinery arranged for us to be able to refer such customers to Dr. Carlon Colker, and for Dr. Colker to review that complaint and provide us with any guidance or information that we needed.

We tried to continue to improve over time the way we took information from callers. Many consumer calls or correspondence were not specific enough for us to determine whether Xenadrine RFA-1[®] was even used, to document the effect reported, or to ascertain information about other possible causes. Sometimes, the consumer indicated improper use of the product, pre-existing conditions that they thought might account for the reported event, or other information indicating that the connection to Xenadrine RFA-1[®] was missing.

Since we at Cytodyne Technologies were not medically trained, however, we engaged Dr. Carlon Colker to help us understand and deal with customer complaints of alleged adverse effects. By engaging a medical doctor to guide us in this regard, we felt we were being very responsible. In addition, Dr. Colker provided responses for Cytodyne Technologies concerning adverse event report forms forwarded to Cytodyne Technologies by the Food and Drug Administration. According to our records, the Company has received complaints of adverse effects from the use of Xenadrine RFA-1[®] over a several year period during which approximately 20 million bottles of the product were sold, each containing 120 capsules, for a total of about 1.2 billion servings. After an extensive review by the Company and its attorneys, our records indicate a total of just under 450 customers contacted Cytodyne Technologies concerning their complaints about the use of Xenadrine RFA-1[®], and most of those were for mild, transitory effects.

It was our policy and practice to advise customers that if they were experiencing adverse effects, they should discontinue the use of the product, and contact their

physician. We made Dr. Colker available to them to learn more about their situation and perhaps share some information with them concerning Xenadrine RFA-1®.

Dr. Colker also advised us of the inherently unreliable nature of adverse event reports and customer complaints, and that many scientific studies showed ephedra-based dietary supplements to be effective and safe within the confines of the clinical studies and when used appropriately. Nevertheless, we paid attention to the information reported to him and reported from him to us, which we have of course turned over to the Committee in full.

I am prepared to try to answer any questions and appreciate the opportunity to provide this information to Congress and the American public.

Mr. GREENWOOD. Thank you, Mr. Conklin.
Dr. Colker?

TESTIMONY OF CARLON M. COLKER

Dr. COLKER. Mr. Chairman, Congressmen, Congresswoman, my name is Carlon M. Colker, M.D., and I welcome this opportunity to assist this subcommittee as it looks into ephedra-based dietary supplements. I am the Medical Director of Peak Wellness in Greenwich, Connecticut. Peak Wellness is a center that provides a variety of services including traditional allopathic medicine, preventive care, nutrition services and physical therapy.

I am an attending physician at Beth Israel Medical Center in New York, and Greenwich Hospital in Connecticut.

While ephedra-based dietary supplements are appropriate for some people, they are populations for whom I think they are not appropriate. First, those persons who have contrary indicated conditions should not take ephedra-based products, particularly without being monitored by a physician. Moreover, I believe there is a significant abuse potential among the youth and athletes.

Young people tend to fall into the scary mindset that more is better. Although efforts are being made by responsible retailers to prevent sales to minors, regulation to further prevent these types of sales would be prudent. Similarly, in general, athletes have a significant abuse potential in that some are willing to go to extremes to get the edge.

Much attention has been paid for serious adverse events reports or AERs, despite no correlation with any available scientific research confirming causation. Though useful as a tool for some aspects of general tolerability, monitoring adverse event reports are recognized by the Department of Health and Human Services as being extremely limited, nonscientific and certainly not conclusive of cause and effect.

According to the published caveats issued by the Center for Drug Evaluation and Research, adverse event reports are not, by themselves, scientific and in no way prove cause and effect. For any given report, AER, there is no certainty that the suspected drug caused the reaction. It further warned the event AER may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.

Finally, accumulated case reports or AERs cannot be used to calculate incidents or estimates of drug risk.

As far as these points apply to dietary supplements, there are many instances to illustrate the limits of this report explained by the Center. Numerous examples of this poor reliability can be

found under the adverse events reporting system, AER's Freedom of Information Reporter, FOI.

One such example cited 877 reactions including convulsions, vomiting chest pain, tachycardia, atrial fibrillation, high blood pressure, myocardial infarction, shock, and numerous other serious symptoms—all attributed to ingestion of vitamin C. Other problems include AER reports of vitamin C "causing" visual problems, thyroid cancer, and even mood swings and foot fracture. So again, while a useful tool on the level of general monitoring, the current AER monitoring system has serious limitations in terms of accurately determining cause and should be interpreted with great care.

I suspect it is for this reason that the Department of Health and Human Services and the General Accounting Office have consistently rejected the insinuation that AERs reliably show cause and effect and that they form any basis to prove the contention that ephedra should be banned. In sharp contrast to this observational data, they have historically relied on the available medical and scientific clinical research. During the Subcommittee's investigation, many references have been made to the recent death of Steve Bechler. His death at such a young age is profoundly upsetting and a tragedy. I feel very sad for Mr. Bechler's wife, his baby, his family and friends. As a physician and sports training specialist, I am concerned when an athlete with Mr. Bechler's significant medical conditions, repetitive history of heatstroke, and apparent lack of conditioning and acclimatization, is pushed or pushes himself beyond all reasonable limits. But as I have said in the past, I do not believe that ephedra caused or contributed to his untimely death. If I saw one case, just one, that conclusively confirmed that ephedra was the cause of a serious injury or death when taken as directed and by an appropriate otherwise healthy individual, I would not be on this panel.

As this committee continues its inquiry on behalf of the American public and the Congress, I hope that my information will be helpful to you, and I look forward to answering your questions.

Thank you.

[The prepared statement of Carlon M. Colker follows:]

PREPARED STATEMENT OF CARLON M. COLKER, PEAK WELLNESS INC.

My name is Carlon M. Colker, M.D., and I welcome this opportunity to assist this Subcommittee as it looks into ephedra-based dietary supplements. I am the Medical Director of Peak Wellness in Greenwich, Connecticut. Peak Wellness is a center that provides a variety of services including traditional allopathic medicine, preventive care, nutrition services and physical therapy. I work in health and fitness primarily as a consultant. I am an attending physician at Beth Israel Medical Center in New York, as well as Greenwich Hospital in Connecticut. I have been appointed by the State of Connecticut to the posts of Assistant Medical Examiner and Probate Court physician. I am a fellow in the American College of Nutrition, and a member of the American College of Physicians and the American College of Sports Medicine, among many other professional medical organizations. I received my undergraduate degree from Manhattanville College in Purchase, New York in 1988, and became a Doctor of Medicine after graduating from the Sackler School of Medicine in New York in 1993, where I was class president and received a variety of honors. I completed my internship and residency in internal medicine at the Beth Israel Medical Center in New York in 1996.

I have always had a self-awareness in health. I play sports, I work out regularly, and I take my nutrition and sports seriously, both professionally and in my personal life. I also take dietary supplements, and I have personally taken a variety of

ephedra-based dietary supplements for the purpose of losing weight. I found that they worked well for me, over and above any adjustments to my diet and exercise. I also use ephedra-based products in my practice.

Among many other things, I have a medical practice, and we have a mission in wellness—doing what we can to improve the quality of our patients' lives and health. This includes helping our patients lose excess weight and helping them get physically fit. In that pursuit, we have been involved in evaluating and utilizing various diet programs, exercise programs, and nutritional supplements, including ephedra-based dietary supplements.

In 1999, we were approached by Cytodyne Technologies, Inc., to perform a clinical evaluation of Xenadrine RFA-1®. We designed a study protocol for a prospective, randomized, double-blinded clinical trial to evaluate the product versus a placebo in otherwise healthy overweight adults. The general intent of our study was to take a limited look at the safety and efficacy of this compound within the confines of the study, with the primary endpoint in efficacy being weight/fat loss.

Thirty overweight adult subjects were randomized into an eight week clinical trial and 16 subjects received Xenadrine RFA-1®. The other 14 subjects received a matched placebo. All subjects were instructed by a Registered Dietician as to specific dieting. In addition, they were instructed in a cross-training exercise program. Twenty-five subjects concluded the study. The Xenadrine group lost a statistically significant amount of fat versus the placebo group. An outside, independent statistical analysis was conducted by a Columbia University, Ph. D. in Biostatistics.

Blood pressure, heart rate, serum chemistry, cholesterol, glucose and caloric intake were measured. Serial electrocardiograms were also performed. There were no notable changes in those safety parameters. We concluded that these findings suggested that Xenadrine was safe and effective within the confines of the study.

Our research was peer-reviewed and eventually accepted for full-length publication in the April 2000 edition of the journal *Current Therapeutic Research*. Peer review acceptance is a recognized indicator of the competency and reliability of a given study. Moreover, this same study, as well as the biostatistician's work, were deemed competent and reliable by a federal judge in a decision rendered in 2000. The federal judge also held that the study was a well-controlled clinical trial, evaluated in an objective manner by persons qualified to do so, and used procedures generally accepted to yield accurate and reliable results. Furthermore, this study was well-rated by the RAND Corporation when it engaged in a full literature review and meta-analysis at the request of the Department of Health and Human Services.

We have clinically investigated other ephedra-based supplements, as well as other dietary supplements. Many times, these studies did not find efficacy or otherwise failed to support the research sponsor's product.

I believe the study we performed for Cytodyne was a competent and reliable study within its confines. I recognize, however, that whatever it added to the scientific literature, it is not perfect and certainly not the "be-all-and-end-all" on the subject. There have been many other studies on ephedra-based dietary supplements and on the effects of ephedra and caffeine for efficacy and weight/fat loss. I believe these studies are critical in understanding the weight loss effects and safety of ephedra-based dietary supplements.

While ephedra-based dietary supplements, including Xenadrine RFA-1®, are appropriate for some people, there are populations for whom I think ephedra-based dietary supplements are not appropriate. First, those persons who have contraindicated conditions should not take ephedra-based products, particularly without being monitored by their physician. Moreover, I believe there is significant abuse potential among youth, and among athletes. Young people tend to fall into the scary mindset that "more is better." Regulations should be designed accordingly to prevent sales to minors. Similarly, in general, athletes have a significant abuse potential in that some are willing to go to extremes to get an edge.

In approximately November 1999, Cytodyne engaged me to serve as a consulting expert. I also continued to maintain my own private medical practice and to consult for other companies. At first, I was hired to review ingredients and articles and to provide the company with feedback, and to answer medical questions as they arose. In addition, I was responsible for putting together academic information and appearing at conferences and educational occasions. When asked, I reviewed label questions and ingredients from time to time. I was also responsible for informing the company if I came across something in the general research of dietary supplements which I thought was important, and for analyzing and reporting general market trends.

During the time I served Cytodyne as a consultant, Cytodyne asked us to perform a comparative study evaluating Xenadrine versus a prescription fat-blocking medication for weight loss in healthy overweight women. The group receiving the

Xenadrine RFA-1® lost significantly greater weight when compared with the group receiving the prescription fat-blocking agent. Our results were published in abstract form.

During the time that I was consulting for Cytodyne, I also was asked, beginning in approximately June 2000, to serve as a referral source for certain company personnel when they felt there was a customer question they could not answer or a customer issue they felt was important to forward to me.

I estimate I have had roughly 60 calls from consumers with such issues. Regarding those customer calls referred to me by Cytodyne, I attempted to learn from the consumer what I could concerning their use of the product, and whether label warnings or other contraindications existed. I periodically reported the results of my conversations and my observations to Cytodyne. I have found that these kinds of customer calls, like adverse event reports to the FDA, are inherently unreliable to indicate what caused the effects. In each of the cases involving Xenadrine RFA-1®, I reported every one of them back to Cytodyne. I answered customer concerns to the best of my ability, told them to discontinue the product when appropriate, and referred them back to their personal physician in every appropriate case.

I was also asked by Cytodyne to look at adverse event reports received from the FDA and help them respond. As I have noted in my correspondence to Kenneth J. Fanci, Ph. D., Director of Scientific Analysis and Support, Center for Food and Applied Nutrition, Department of Health and Human Services, some of the reports seemed serious, but I could not rule out the possibility that these were due to some other cause.

I am also aware that Cytodyne developed a form for gathering information from customers who initially made contact with the company before the customers contacted me. Though I was not involved in the development of this form, the form was simple enough for non-medical operators to get important basic information. As I understand it, Cytodyne developed and used this form and informed callers who were concerned about possible side effects to discontinue the use of all products and seek medical advice. Given that, I believe that Cytodyne acted responsibly. I am aware that Cytodyne reports having sold over 20 million bottles of Xenadrine. In light of that, the very small number of calls, and the dispersion of those calls over time, and in light of the types of calls and information I received, the information does not indicate to me a disproportionate adverse event profile.

Though useful as a tool for some aspects of general tolerability monitoring, AERs are recognized by the Department of Health and Human Services as being extremely limited, nonscientific, and certainly not conclusive of cause and effect. According to the published "Caveats" issued by Center for Drug Evaluation and Research,

Adverse events [AERs] are not by themselves scientific and in no way prove cause and effect... For any given report [AER], there is no certainty that the suspected drug caused the reaction.

They further warn

The event [AER] may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.

Finally,

Accumulated case reports [AERs] cannot be used to calculate incidence or estimates of drug risk.

As far as these points apply to dietary supplements, there are many instances to illustrate the limits of this reporting as explained by the Center. Numerous examples of this poor reliability can be found under the Adverse Events Reporting System (AERS) Freedom of Information (FOI) Report. One such example cited 877 reactions—including convulsions, vomiting, chest pain, tachycardia, atrial fibrillation, high blood pressure, myocardial infarction, shock, and numerous other serious symptoms—all attributed to ingestion of vitamin C. Other problems include AER reports of vitamin C "causing" visual problems, thyroid cancer, and even mood swing and foot fracture.

So again, while a useful tool on the level of general monitoring, the current AER monitoring system has serious limitations in terms of accurately determining cause and should be interpreted with great care.

Perhaps the sharpest criticism of ephedra using AERs as a basis for conclusion was published in the January 2002 issue of *Mayo Clinic Proceedings* in which they looked at adverse cardiovascular events as they relate to ma huang (Mayo Clin Proc. 2002;77:12-16). They admit:

Our report has the limitation of being an observational study and as such does not definitively establish the relationship between ma huang use and the risk of adverse cardiovascular events.

Furthermore, they also said that their report fails to definitively establish ... a causal relationship between the respective agents and the observed adverse cardiovascular events. Additionally these reports provide no insight on the potential biologic mechanisms of the adverse effects of ma huang...

I suspect it is for this reason that the Department of Health and Human Services and the General Accounting Office have consistently rejected the insinuation that AERs reliably show cause and effect and that they form any basis to prove the contention that ephedra should be banned. In sharp contrast to this observational data, they have historically relied on the available medical and scientific clinical research.

Numerous clinical studies conducted by researchers like Daly, Costello, Molnar, Dulloo, Dollery, Bell, and White, just to name a few, have clearly researched and noted both the relative safety and efficacy of ephedra and certain ephedra-based products when taken as directed and by individuals appropriate to do so, and refute the impact of AERs on the issue of safety.

During the Subcommittee's investigation, many references have been made to the recent death of Steve Bechler. His death at such a young age was a profoundly upsetting tragedy. I feel very sad for Mr. Bechler's wife, baby, family and friends. As a physician and sports training specialist, I am concerned when an athlete with Mr. Bechler's significant medical conditions, repetitive history of heat stroke, and apparent lack of conditioning and acclimatization, is pushed or pushes himself beyond all reasonable limits. I do not believe that ephedra caused or contributed to his untimely death.

As this Committee continues its inquiry on behalf of the American public and the Congress, I hope that my information will be helpful to you, and I look forward to answering your questions.

Mr. GREENWOOD. Thank you, Dr. Colker.
Mr. Occhifinto?

TESTIMONY OF ROBERT OCCHIFINTO

Mr. OCCHIFINTO. Mr. Chairman, and other members of the subcommittee, my name is Robert Occhifinto. I am the President of NVE Pharmaceuticals in Newton, New Jersey.

NVE manufactures dietary supplements including products that contain ephedra. I am here today to assist the subcommittee in its review of the safety and effectiveness of ephedra products.

NVE manufactures numerous dietary supplements. In addition to our ephedra products I am here to discuss today, we manufacture energy drinks and protein bars.

We are a substantial employer in a rural area in Sussex County, New Jersey. At least 100 families in that area depend on NVE for their livelihood.

Mr. Chairman, I appreciate the opportunity to testify before the subcommittee today regarding ephedra.

Let me state first that I strongly believe in the safety and effectiveness of NVE's products. The overwhelming scientific evidence is that ephedra is safe and effective when used as directed. Ephedra has been used for thousands of years. The Rand Corporation in a study commissioned by the Department of Health and Human Services at the request of FDA recently reported on the safety and effectiveness of ephedra. The Rand report examines all relevant clinical trial literature. It concludes there is no evidence that ephedra is unsafe when used as directed for weight loss. This government report does not suggest the removal of ephedra from the marketplace.

Between 12 and 17 million Americans consume more than 3 billion servings of ephedra products every year. Against that level of usage, the Rand report identified only 22 serious events where ephedra could not be ruled out as a potential cause.

The safety record of ephedra is comparable and in some cases better than many of the over-the-counter pharmaceutical products. For example, a recent study sponsored by NIH found that acetaminophen, the active ingredient in Tylenol, is now the leading cause of acute liver failure. Despite this finding, the study concludes that acetaminophen is not dangerous. The authors recommend more education to alert both patients and doctors not to exceed the recommended dose. Acetaminophen continues to be used as the active ingredient in several widely used pain medications.

NVE has retained the Weinberg Group, a respect scientific consulting firm, to review scientific on ephedra for us. The Weinberg Group's Dr. Rosanne McTyre, a Johns Hopkins University trained epidemiologist with more than 20 years experience examined the Rand report in detail. This report is attached to my written testimony as Exhibit B.

Dr. McTyre concludes that the current state of knowledge regarding the safety of ephedra-containing products does not warrant the removal from the marketplace. According to Dr. McTyre, the document adverse health effects of ephedra are minor, temporary and similar nature to drinks containing caffeine. Serious events such heart attacks and strokes are not conceivably links to ephedra use.

Ephedra has a mild stimulant effect and is effective for weight reduction. The Rand report concluded that ephedra containing dietary supplements were effective in weight loss of 2 pounds per month for a 6 month period. Ephedra is an important tool for assisting individuals in connection with weight management.

The subcommittee should not overlook the fact as it considers these issues. Obesity is a serious public health problem with staggering consequences. Recent studies indicate that in the year 2000 about 64 percent of adult Americans were overweight. A recent U.S. Surgeon General report predicts that being overweight will soon match cigarette smoking as the leading cause of premature death and disability in the United States.

We recognize that the proper use of ephedra is essential. NVE places extensive warnings on every ephedra-containing product it sells. NVE labels warn consumers that consumptions of amounts in excess of label directions could pose a risk of severe adverse event, including stroke or heart attack. Our labels warn against taking this product if you are pregnant, nursing, have a family history of heart or thyroid disease.

I believe that were the first manufacturer in our industry to put warning against use by minors our labels. We market our products responsibly and are committed to preventing abuse.

We believe our products are safe and effective and satisfy real consumer desire for weight management products.

NVE is committed to the safety of its products to making sure that minors do not abuse them. To demonstrate our commitment, I have advised the subcommittee by letter this morning that NVE will provide funding to NIH for another appropriate government body to independently study the long term safety of ephedra.

We also undertake a public education campaign to alert minors, their parents, their schools and their coaches against the use ephedra products by minors. This education campaign will also encourage the safe and responsible use of ephedra by adults.

We hope that these important commitments by NVE will assist the subcommittee and other government agencies in their important in this area.

I am happy to answer any questions regarding our ephedra products the subcommittee may have.

Mr. GREENWOOD. Thank you, Mr. Occhifinto.

Ms. Fox?

TESTIMONY OF ROSEANN FOX

Ms. FOX. Mr. Chairman, and other members of the subcommittee, my name is Roseann Fox, and I am a customer service representative at NVE Pharmaceuticals in Newton, New Jersey. I have worked at NVE for 7 years and I have worked as a customer service representative since 1999. As a customer representative I respond to questions about how to take our products, lost or damaged products and health concerns. When individuals call with health concerns, I do not give them medical advice. Instead, I advise them of the warning on the labels and direct them to consult a physician.

I am happy to answer any questions regarding customer relations at NVE that the subcommittee may have.

Mr. GREENWOOD. Thank you, Ms. Fox.

The Chair recognizes himself for 10 minutes for the purpose of questioning. And I am going to start with you, Mr. Occhifinto.

You do not have a college degree, medical degree or any type of graduate degree relating to pharmacology, chemistry or nutrition, correct?

Please bring the microphone over.

Mr. OCCHIFINTO. No, Mr. Chairman, I do not. I have been in this industry for 23 years and have practical on-the-job training.

Mr. GREENWOOD. All right. Is it true that you formed NVE Pharmaceuticals in 1980 upon graduation from high school?

Mr. OCCHIFINTO. Yes, it is.

Mr. GREENWOOD. Where did you get the funds to begin this business at 18 years of age?

Mr. OCCHIFINTO. I worked for Sears Roebuck and saved up money and opened up in a little 10 by 10 store.

Mr. GREENWOOD. Okay. At the time your formed NVE was a distributor of diet products made under their label?

Mr. OCCHIFINTO. I used to distribute products that were manufactured by others in the small store that I had.

Mr. GREENWOOD. Okay. Is it true that NVE has never employed a medical doctor, pharmacologist or chemist to formulate ephedra containing products?

Mr. OCCHIFINTO. Yes, it is.

Mr. GREENWOOD. Okay. Is it not true that the committee staff questioned your general counsel, David Caldwell, on who was responsible for determining the formulation of NVE's ephedra-containing products and that it was represented to the committee that you were the only person? Is that correct?

Mr. OCCHIFINTO. Mr. Chairman, there is a lot of literature out there about the formulation of the products that we manufacture. Yes, it is.

Mr. GREENWOOD. Okay. But you are the guy that does that without the medical degree or training, is that right?

Mr. OCCHIFINTO. Yes, I am.

Mr. GREENWOOD. Okay. As the founder and president of NVE, who runs the company in your absence?

Mr. OCCHIFINTO. Walter Orichat is vice president.

Mr. GREENWOOD. Okay. It is our understanding that 1994 you were convicted of a Federal charge of money laundering in New Jersey and sentenced to 8 months prison, is that correct?

Mr. OCCHIFINTO. No, it is not.

Mr. GREENWOOD. Okay. Could you correct the record?

Mr. OCCHIFINTO. In 1991, approximately 12 years ago, I sold a regulated compound without filing the paperwork. And in 1996 I went away for approximately 18 months and served my time.

Mr. GREENWOOD. For? What was the conviction?

Mr. OCCHIFINTO. The conviction was for money laundering.

Mr. GREENWOOD. Okay. So that when I said it is our understanding in 1994 you were convicted of a Federal charge of money laundering and spent 8 months in prison, is that—what is incorrect about that?

Mr. OCCHIFINTO. It was 18 months.

Mr. GREENWOOD. Eighteen months?

Mr. OCCHIFINTO. Yes.

Mr. GREENWOOD. That is what I said.

Mr. OCCHIFINTO. I thought you said 8 months, I am sorry.

Mr. GREENWOOD. Well, I may have, but I meant to say 18 months.

All right. During those 18 months you were in prison who was running NVE and making the business decisions?

Mr. OCCHIFINTO. Roland Bossey.

Mr. GREENWOOD. Okay. Is it not correct that the money laundering charges stemmed from you supplying ephedra in bulk to a methamphetamine dealer?

Mr. OCCHIFINTO. I do not know what happened to the material that I supplied. I supplied it to somebody and I was charged with supplying material without filling out the paperwork.

Mr. GREENWOOD. You do not know who you were supplying it to?

Mr. OCCHIFINTO. I know the gentleman I supplied it to. I do not know what he actually did with the material. I know the allegations of what he did with the material.

Mr. GREENWOOD. You do not know whether he was methamphetamine dealer?

Mr. OCCHIFINTO. Mr. Chairman, I know the allegations that he was. I do not know the man personally.

Mr. GREENWOOD. Okay. Presumably since you have had over 20 years in the dietary supplement industry and are responsible for formulating over 80 products that contain ephedra, you would be aware of the various combinations that ephedra or ephedrine may be used with to produce a drug?

Mr. OCCHIFINTO. Ephedra is a dietary supplement, it's not ephedrine, so it is not the same—the same thing on health for ephedra as ephedrine, Mr. Chairman.

Mr. GREENWOOD. Has not the DEA made you aware beginning in at least 1994 of the fact that your ephedrine and ephedra tablets have ended up being seized in illegal methamphetamine labs?

Mr. OCCHIFINTO. Yes, they have.

Mr. GREENWOOD. Okay. Were you aware of that before the DEA let you know about it?

Mr. OCCHIFINTO. I was aware of it by—the DEA would always inquire and we would always help the DEA in whatever they needed information and requiring where shipments went to. And we would report to DEA the shipments—

Mr. GREENWOOD. But you are testifying under oath here today that you never knowingly supplied any of your products for the purpose of them being used to produce illegal street drugs?

Mr. OCCHIFINTO. Mr. Chairman, we discussed my conviction. My conviction I knowingly sold ephedrine hydrochloride to somebody who used it improperly. And after that and before that, I know nothing else other than that.

Mr. GREENWOOD. Okay. And you were also convicted in the early 1990's of a prior Federal criminal offense involving importation of a controlled substance, hashish oil?

Mr. OCCHIFINTO. Yes, Mr. Chairman.

Mr. GREENWOOD. And you were sentenced to house arrest for 18 months?

Mr. OCCHIFINTO. No, I was not. I was on a trip with a friend to Jamaica and he gave me a bottle of liquor to bring back, he told me that it was because of Customs, he did not want to pay the small duty on it. Could I carry it back. When I got back I was aware by the Customs officer told me that there was hash oil in it. We were both arrested at the airport, I believe in Tampa. And the gentleman who did that took the responsibility for that, and I got home confinement of 8 months.

Mr. GREENWOOD. Eight months, not 18?

Mr. OCCHIFINTO. Yes.

Mr. GREENWOOD. Okay.

Mr. OCCHIFINTO. That was 12 or 12 years ago, Mr. Chairman.

Mr. GREENWOOD. Very well.

Let me ask you a question, is it your company that marketed products with names like Black Beauty and Yellow Jacket?

Mr. OCCHIFINTO. We no longer market those products.

Mr. GREENWOOD. But you did, right?

Mr. OCCHIFINTO. Yes, we did.

Mr. GREENWOOD. Okay. When you decided to name, where did you get the idea of the name of Black Beauty? Is that from the book?

Mr. OCCHIFINTO. Just from the Disney character.

Mr. GREENWOOD. It was?

Mr. OCCHIFINTO. Most of the products depict energy.

Mr. GREENWOOD. Okay. And you were not aware, you chose—what was it about the Disney character that you thought it would make a nice association with a weight loss product?

Mr. OCCHIFINTO. Just the—

Mr. GREENWOOD. The svelte nature of the horse or what was it?

Mr. OCCHIFINTO. Well, the nature of the horse. That product was more designed as an energy product than a weight loss product.

Mr. GREENWOOD. Okay. And were you aware before you decided to label this product Black Beauty that was a common street drug called Black Beauty?

Mr. OCCHIFINTO. No, it was not in my knowledge, no.

Mr. GREENWOOD. I knew that when I was in college. I mean, it was pretty common knowledge that there were products of that name that were illegal street drugs. You did not know that?

Mr. OCCHIFINTO. Mr. Chairman, I—that was brought to my attention about Black Beauty and the name Yellow Jacket at a trade show sometime later after I introduced the products. After doing some research on it, with the Yellow Jacket name, I found out that it was a barbiturate. My product had a picture of a bee, it was the color, yellow and black with stripes on it. Looked like a bee. And was for energy. I did not really think there was a problem naming it that.

Later on I found out—

Mr. GREENWOOD. I am just trying to figure out if you were—what your marketing intent was when you came up with those kinds of names, whether that was a way that you thought that would appeal for young people, for instance?

Mr. OCCHIFINTO. I do not condone marketing to young people. I am one of the first people to come out with warnings not to sell my products to minors.

Mr. GREENWOOD. Okay. Have you been told by any governmental agency that you were a target of any criminal probes?

Mr. OCCHIFINTO. To the best of my knowledge, no.

Mr. GREENWOOD. Okay. Is your current company currently under investigation by the FDA?

Mr. OCCHIFINTO. I believe we are trying to work something with an inspection that we had with the FDA several weeks ago.

Mr. GREENWOOD. What was the issue there?

Mr. OCCHIFINTO. We manufactured—we custom manufactured a product called Stamina Rx for a company out of Atlanta, Georgia where they supplied us all the raw materials. We simply blended them, compounded them and shipped them back to them and to distributors.

The FDA came in and alleged that there was a product called Terdalophil in that product.

Mr. GREENWOOD. There was what?

Mr. OCCHIFINTO. A product—that it was adulterated with a product called Terdalophil.

Mr. GREENWOOD. And what is that?

Mr. OCCHIFINTO. I believe it is a male potency product.

Mr. GREENWOOD. Okay. And is that product considered a prescription drug? Do you need a prescription to get that?

Mr. OCCHIFINTO. I believe it is.

Mr. GREENWOOD. Did you know that at the time of your manufacturing?

Mr. OCCHIFINTO. We were not provided with Terdalophil. We were provided with herbal products. We manufactured it. The FDA brought it to our attention that the material was contaminated with Terdalophil or it had gotten there some other way. We do not know how it got in the product. We did not put it in the product.

Mr. GREENWOOD. All right. We are concerned about the lack of any documentation that you have provided the committee concerning the decisions surrounding the formulation and marketing of your ephedra-containing products. It is very hard to believe that a company in existence for over 20 years, as you have described, has absolutely no documents to support its decisions concerning formulation of products that are ingested by human beings, products that have been shown to have adverse health effects in people.

Committee staff made numerous attempts to receive responsive information from your company and NVE first through your counsel and then by your own written representations provided the committee with not one shred of documentation concerning how you, Mr. Occhifinto, went about deciding to formulate these products. Let me give you an example.

There is a document at Tab 57. It is a June 10—you see that book there. If you want to refer to it. It is Tab 57.

June 10, 2003 letter to committee from Mr. Occhifinto question number 21 page 6, “After numerous attempts to receive all documents relating to your formulation decisions and told by your counsels that there was nothing other than perhaps your own notes, the committee requested this follow up information. Provide all of Bob Occhifinto’s handwritten notes relating to the formulation of any ephedra product” and Mr. Occhifinto’s response was there are none. Is that correct, Mr. Occhifinto, that in the 87 ephedra products that your company has sold in the marketplace over the years you are telling this committee under oath that absolutely no documents exist that detail the decisionmaking and the formulation of the products?

Mr. OCCHIFINTO. Mr. Chairman, we have extensive paperwork on the formulas. There are no notes that were kept on any of the products when they were manufactured. We have the formulas and the backup paperwork every time we make a batch that product with the formula.

Mr. GREENWOOD. Did you supply this committee with those documents?

Mr. OCCHIFINTO. I do not believe that was what was asked. And we did supply the documents for the formula.

Mr. GREENWOOD. I am advised by counsel that we specifically requested the formula cards from your company and that those were not supplied.

Mr. OCCHIFINTO. Mr. Chairman, if they were not supplied, we can supply them to you. I think they were supplied, though, because we never—there was—what we understood was the notes about the formulas.

Mr. GREENWOOD. No, that was a last ditch effort to get documentation from you because we had been told that there were no documentation with regard to formulations with the possibility—the only possibility being that of your personal notes.

Mr. OCCHIFINTO. Mr. Chairman, if they were not supplied, we will supply them to you. There is no problem with that at all. It must have been a miscommunication.

Mr. GREENWOOD. Well, we will have immediately at the conclusion of this hearing before your attorney leaves the room if you would be so kind, we would like you to consult with our counsel

and make sure that that offer by Mr. Occhifinto is fulfilled as promptly as possible.

The Chair recognizes the gentlelady from Colorado for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Occhifinto, just a follow up on the Chairman's questions. How long were Yellow Jacket and Black Beauty on the market, how many years?

Mr. OCCHIFINTO. I do not know exactly. Approximately 2 to 3 years.

Ms. DEGETTE. Two to 3 years each?

Mr. OCCHIFINTO. I believe so.

Ms. DEGETTE. And how much money did your company make from each of those products during the period they were on the market?

Mr. OCCHIFINTO. I do not know the numbers for that.

Ms. DEGETTE. Can you please supplement?

I would ask unanimous consent that he supplement his answer with that information within 20 days, if that would be all right.

Mr. OCCHIFINTO. That is no problem.

Ms. DEGETTE. Thank you.

Why did you withdraw these products, one named after a Disney character and the other after a bumblebee, from the market?

Mr. OCCHIFINTO. It was brought to my attention that marketers in the Netherlands were selling them as street drug alternatives. As soon as it was brought to my attention, at great expense to my company, I voluntarily recalled the product off the market.

Ms. DEGETTE. Okay. And you had no knowledge before that of any other kind of implications of those names in this country? That is your testimony under oath today?

Mr. OCCHIFINTO. I do not understand what you mean "implications."

Ms. DEGETTE. Well, you told Mr. Greenwood that you did not know that Yellow Jacket and Black Beauty were the names of illicit drugs in this country prior to that.

Mr. OCCHIFINTO. I was made aware that some people use them as slang terms a while ago, and at that time—

Ms. DEGETTE. But you did know that?

Mr. OCCHIFINTO [continuing]. They told me—that was 20 or 30 years ago. I was—20 or 30 years ago, you know, I was 10 or 20 years old. It never occurred to me. I never saw drugs like that. I did not know that.

Ms. DEGETTE. So your answer is you really did not know of any illicit implications before you found out about this situation in the Netherlands and withdrew them from the market? Yes or no.

Mr. GREENWOOD. Will the gentlelady yield?

Ms. DEGETTE. Sure.

Mr. GREENWOOD. Your testimony under oath is that you decided to use a Walt Disney character for a name for your products, that you had no notion that Black Beauty had been used as a street drug and you did not pick Dumbo, you did not pick Pinocchio, you did not pick Goofy, you picked Black Beauty and it was just an amazing coincidence? That is your testimony?

Mr. OCCHIFINTO. Not until afterwards was I—was I apprised that that was—that was the name of it. And I did not think it was a problem, because 20 or 30 years had gone by before that product was even on the—out there as a street drug.

Ms. DEGETTE. Reclaiming my time.

I asked you a simple question. You said you withdrew those drugs from the market when you found out there was an issue in the Netherlands. Did you know about those implications before that? Yes or no.

Mr. OCCHIFINTO. I knew previously that there—

Ms. DEGETTE. Thank you. Thank you.

Mr. OCCHIFINTO [continuing]. Was allegations.

Ms. DEGETTE. Okay.

Mr. TELLER. May he finish his answer, ma'am?

Ms. DEGETTE. Thank you, sir.

Now, Mr. Schreck, you said that your company prohibits the sale of Metabolife to minors, correct?

You need to turn on your microphone, sir. That is okay.

Mr. SCHRECK. We favor the barring of sales to minors.

Ms. DEGETTE. No, but you said in your testimony you prohibit the sale of Metabolife to minors, is that right? Or did I mishear you.

Mr. SCHRECK. I do not think I said that, but I may have, Congresswoman.

Ms. DEGETTE. How do you enforce that? Do you tell your distributors and the retail sales not to sell it to minors?

Mr. SCHRECK. We communicate with them that we do not wish to sell to minors and we do communicate to all of our sales people this. And also—

Ms. DEGETTE. You have written protocols? I am sorry, I do not mean to be rushing. They only give me a certain amount of time. Do you have written protocols that you give to your sales people and your distributors and the sales outlets saying do not sell this to minors?

Mr. SCHRECK. We do not do that written protocol. We do have verbal communications with them.

Ms. DEGETTE. So there is nothing in writing.

Mr. SCHRECK. And considering that our customers are with the WalMarts of the world, we do not have great control over enforcing what they do.

Ms. DEGETTE. Right. So you really cannot enforce who your product is sold to, correct?

Mr. SCHRECK. Whoever WalMart will sell it to and other people—

Ms. DEGETTE. I am right? Okay. Thanks.

Now, you also do not support the sale of Metabolife to athletes, do you?

Mr. SCHRECK. No.

Ms. DEGETTE. Okay. How many doses of Metabolife do you sell per year on an average?

Mr. SCHRECK. I think we have servings of, as we mentioned earlier, over a 5 year period our servings are approximately 50 million bottles or 4.5 billion tablets. And if you would say that there are

6 a day, you would probably be talking about—I am rounding off in my head, something like 80 million servings.

Ms. DEGETTE. Okay. Over a 5 year period, right?

Mr. SCHRECK. Yes.

Ms. DEGETTE. Now, I assume that you showed us a poster of the Metabolife bottle, you are familiar with the label on Metabolife, is that right?

Mr. SCHRECK. Reasonably familiar.

Ms. DEGETTE. Okay. Because on the front, I was just looking at it and there is a little seal here.

Mr. SCHRECK. Yes.

Ms. DEGETTE. Are you familiar with that seal, because it looks like some seal of approval and it says “Q.A.” I am wondering what that means.

Mr. SCHRECK. To tell you the truth, Congresswoman, I have been with the company 2 months. I do not have an answer for that.

Ms. DEGETTE. Mr. Hermann, do you know what Q.A. means? Do you know what this seal means?

Mr. HERMANN. Q.A. I believe you are referring to the Aceris label that is on this——

Ms. DEGETTE. There is a little seal on—yes. A-C-E-R-I-S.

Mr. HERMANN. Yes. Aceris is an independent company that will come in and do a review of your GMPs and also review the product that you are manufacturing. I believe we had that done throughout——

Ms. DEGETTE. You had them come. Who are they? Do you hire them to come in and look at your product?

Mr. HERMANN. Yes. You do pay them for that. They come in and do an independent analysis of your manufacturing facilities.

Ms. DEGETTE. And based on what standards?

Mr. HERMANN. They look at food GMPs primarily. They also look at SOPs.

Ms. DEGETTE. I do not know what those acronyms mean, sir. I am sorry.

Mr. HERMANN. General manufacturing practices.

Ms. DEGETTE. Thank you.

Mr. HERMANN. Or good manufacturing practices.

Ms. DEGETTE. Okay. So they are a trade organization?

Mr. HERMANN. I am not sure.

Ms. DEGETTE. Okay. You do not know.

And it says here “Quality ingredients, manufacturing, labeling.” Is that what they determined?

Mr. HERMANN. That is on their seal, yes, ma’am.

Ms. DEGETTE. Okay. And it says Q.A., what does that mean? Do you know?

Mr. HERMANN. That is just part of their seal logo.

Ms. DEGETTE. Okay. Because it looks to me like this is like a seal of approval. Is that why you put that on there?

Mr. HERMANN. They have—they do come in and approve those facilities. And with the manufacturing of 356 before we would allow a third party manufacturer to manufacture our product, we do have—we have had an independent review by Aceris to assure that people are following their procedures.

Ms. DEGETTE. Okay.

Mr. HERMANN. Largely that is what we are looking at.

Ms. DEGETTE. Okay. Thank you, sir.

And so you put this on the Metabolife bottle to tell the consumer that someone has certified something here, right? I mean, that is why you put it on the bottle, right?

Mr. HERMANN. That product has been certified by Aceris, yes, ma'am.

Ms. DEGETTE. Thank you. Okay.

Dr. Boozer, I want to ask you a few questions. There were 2 studies that were done and they included between the 2 of them 234 men and women who were overweight but otherwise healthy, correct?

Ms. BOOZER. That is right.

Ms. DEGETTE. And everybody agrees you did not put people in this survey who had heart problems or other kind of problems that would be counter-indicated by this drug, right?

Ms. BOOZER. That is correct.

Ms. DEGETTE. Or this substance?

And so you do not really know what the effect of ephedra would be on individuals who had heart problems or other kinds of problems, right?

Ms. BOOZER. No, we do not.

Ms. DEGETTE. And do you think that a study of—2 studies with 234 people out of the admittedly millions of doses of this that have been sold is sufficient to come up with a scientific conclusion that this substance is safe and effective?

Ms. BOOZER. I have never made that statement that it is safe and effective.

Ms. DEGETTE. Okay. I know you never did. I wanted to ask you if you thought it was.

Ms. BOOZER. I think that the study had enough power or there is a statistical method that one can use to determine whether you have enough subjects included in the study to find the end points that you are looking for.

Ms. DEGETTE. Right. And the end points you were looking for among a small section of health, overweight adults if they lose weight?

Ms. BOOZER. That is right. That is right. So—

Ms. DEGETTE. Now there were also some people who withdrew from the study because, and I am quoting from the conclusion of your report, "The tested product also produced several untoward side effects leading some actively treated subjects to withdraw from the study," right?

Ms. BOOZER. That is the 8 week study, yes.

Ms. DEGETTE. Yes. So some people withdrew from it because there were side effects?

Ms. BOOZER. That is correct.

Ms. DEGETTE. Now, the problem we have here is this is not an FDA approved drug so we cannot limit the distribution of this substance to, say, people at health clubs, people who have heart problems, children. And you did not take any of that into effect? That was not the purpose of your study, was it?

Ms. BOOZER. That is exactly right. That was not the purpose of our study.

Ms. DEGETTE. And one last question, because I read over your CV and your list of publications. You are really, and by the way, a very highly qualified nutritional researcher, correct?

Ms. BOOZER. In the field of obesity, yes.

Ms. DEGETTE. In the field of obesity. You are not educated or pretend to be a researcher in the effect of drugs on the human body or that is not what this study was about, right?

Ms. BOOZER. You are right in saying that I do not have those qualifications. Some of the other co-authors on the papers do have those qualifications.

Ms. DEGETTE. Thank you very much.

Mr. Chinery, I just have a couple of questions for you. You were responsible for the original formulation of Xenadrine, is that how you pronounce it? Xenadrine?

Mr. CHINERY. Xenadrine.

Ms. DEGETTE. Xenadrine. Thank you.

We you not?

Mr. CHINERY. I actually had worked with—in collaboration with the people at our manufacturing laboratory and their product development staff.

Ms. DEGETTE. What were the names of the people who helped you develop Xenadrine?

Mr. CHINERY. The primary person that I worked directly with, his name is Mel Rich.

Ms. DEGETTE. And is Mel a pharmaceutical, does he have a Ph.D? What is his educational and scientific background?

Mr. CHINERY. I believe he's a registered pharmacist.

Ms. DEGETTE. Okay. And what was his role in developing Xenadrine?

Mr. CHINERY. He actually defined the specific formulation.

Ms. DEGETTE. Oh. So he developed the formula, not you?

Mr. CHINERY. Well, he defined the precise formulation. I had concepts that I presented to him and then he finalized that formulation.

Ms. DEGETTE. Okay. Let me just ask one more question.

What is your academic background, sir?

Mr. CHINERY. Actually, I started work on the dietary supplement industry part time when I was in high school and I graduated high school and worked for dietary supplement company full time at that point.

Ms. DEGETTE. So your academic background is a high school degree, correct?

Mr. CHINERY. Correct.

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognize the gentleman from Oregon for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman.

Dr. Boozer, did the findings of your 6 month study show that ephedra is safe?

Ms. BOOZER. I have refrained from using the word safe in defining the results of the study for this reason: I think that it is a word that can be generalized. And I have said in the papers that I do

not think our results can be generalized beyond the types of people we studied.

Mr. WALDEN. So nobody on this panel should ever use your study to say their product is safe, is that accurate?

Ms. BOOZER. I would not recommend that they do that.

Mr. WALDEN. Okay.

Ms. BOOZER. I do not use that word.

Mr. WALDEN. Sometimes it is held up as the gold standard, the best scientific research out there. And I read some of the testimony saying we have got all these studies saying it is safe. But yours would not be a study you would stand behind to say that this drug is safe? Is that your testimony?

Ms. BOOZER. I do not use the word safe, because as I said—

Mr. WALDEN. And you would not recommend anyone else to use it?

Ms. BOOZER. I am not saying that it is unsafe either. What I am saying is that it is somewhat a philosophical issue. When you say something safe, I think it is interpreted more broadly than I believe the results of this study should be interpreted.

Mr. WALDEN. Thank you.

I guess there are a lot of advertisements out there that might lead one to believe in the consumer market that some of these products are safe, so it is good to hear that you say your study says neither safe or unsafe. That is what you are saying, correct?

Ms. BOOZER. Well, I choose the words pretty carefully in the study. And I said I believe that when used as directed by the type of people that were included in this study for the length of time and at the dosages that we used it—

Mr. WALDEN. Right.

Ms. BOOZER [continuing]. There were no serious adverse effects.

Mr. WALDEN. Okay. Thank you.

Mr. Chinery, I read with interest, obviously, your comments quoting Dr. Baden—is it Badden or Baden?

Mr. CHINERY. Baden.

Mr. WALDEN. Baden.

And you quote, and I think one of the other persons on the panel used the same terminology about severe obesity when it comes to Steve Bechler. It is in your testimony quoting Dr. Baden.

Mr. CHINERY. Yes.

Mr. WALDEN. And one of the other panel members used it to describe to Mr. Bechler's condition. His family earlier today testified he was 10 pounds overweight. Do you agree with that?

Mr. CHINERY. The only information that I have had available to me is the information that was provided by Dr. Perper's office. And I believe the specific term "morbid obesity" came from the information supplied by him.

Mr. WALDEN. Really? Did you or your attorneys have access to all the public information available? Was there anything that the autopsy investigation found that you did not have access to that you are aware of?

Mr. CHINERY. It is possible. I do know that the information from Dr. Perper's office indicated a body weight of 320 pounds.

Mr. WALDEN. And was that—why was it 320 pounds?

Mr. CHINERY. I am not sure why.

Mr. WALDEN. You do not know why, but you can use and others can backup the fact that 320 made him morbidly obese, correct?

Mr. CHINERY. Well, again—

Mr. WALDEN. It is what you said per Dr. Baden.

Mr. CHINERY. It is based on a term used by Dr. Perper.

Mr. WALDEN. Okay. I appreciate knowing that. Because I have before me, and I will ask to be entered in the record, apparently it is already entered into the record, information from Dr. Perper, dated July 23. He has now seen the information that you present in your testimony. And it says, among other things, he takes quite a number of exceptions.

It says Dr. Baden noted correctly the patient weight at the time of the autopsy was 320 pounds and that he was 6'2" in height and therefore it concluded that he was morbidly obese. However Dr. Baden admitted 2 important facts which were, and I quote, "The fact that Mr. Bechler's weight 3 days before his demise was 250 pounds and no individual, no matter how much would eat can gain 70 pounds of weight in 3 days."

Furthermore, Mr. Bechler's gastrointestinal tract was empty. He ate very little, if at all, during the 2 to 3 days preceding his demise. At the time of the autopsy Mr. Bechler was excessively bloated and deamatoose. This bloating was a result of both infusion of resuscitation fluids and his kidney failure with lack of urination.

I think it is terribly misleading to use the terminology that was used to say that part of his death was caused by severe obesity. He was 10 pounds overweight 3 days before.

"Also, Mr. Baden claims that ephedra played no role in the death of Mr. Bechler and that in general ephedra is not and cannot be linked to the occurrence of heatstroke. In support of that he advanced a number of statements and arguments refuted by the following facts."

Page 2 of this report, and again I am quoting from Dr. Preper.

"Dr. Baden indicates that he had no access to ENT-Fire Rescue records on February 16, the North Ridge Medical Center Hospital records of February 16 and 17, past medical records, the autopsy microscopic slides and photographs, and the interviews of the witnesses to Mr. Bechler's collapse and initial treatment." Okay. But then Dr. Preper goes on to say "In the telephonic conversation with Dr. Baden I informed him of the willingness of my office and of myself to fully disclose and deliver all public records or materials. As a matter of fact the attorneys for Cytodyne obtained all open records requested."

Mr. CHINERY. My counsel is shaking his head no, which would indicate to me that maybe there is an inconsistency with that.

Mr. WALDEN. We will find out.

Dr. Boozer, in the FDA's peer review of your study there are several points that come out. And I would like to ask you about those, because I think it is important to this whole issue.

Ms. BOOZER. Well, Congressman, I should point out that the FDA has not provided me with a copy of that review.

Mr. WALDEN. Well, we will certainly make it available. It is in the book, is it not? Do we have a tab number?

We will make it available to you.

Were you aware they were having outside people do peer review?

Ms. BOOZER. I was, and they promised that they would give me a copy of the report before it went public.

Mr. WALDEN. Okay. We will get a tab number for you here. And I believe that someone in the company had some—as part of the deal to get information, the actual data, there was some involvement with your company, correct?

Ms. BOOZER. Columbia University?

Mr. WALDEN. No. To select the outside panel? The company, was it Cytodyne had the opportunity to—Metabolife, I am sorry. Had the opportunity to participate in the selection of the scientists, correct?

Ms. BOOZER. I do not think Metabolife had anything to do in selection of the scientists on that panel. I think the——

Mr. WALDEN. Really?

Ms. BOOZER. Mr. Wes Signer was counsel for the Ephedra Education Council. I think he was the person who was negotiating the arrangement of the panel.

Mr. WALDEN. Is not Metabolife a member of that council?

Ms. BOOZER. They may be. I do not know.

Mr. WALDEN. Okay. If you would turn to Tab 113 in the book, that may help. I assume——

Mr. HERMANN. Congressman, I am sorry.

Mr. WALDEN. Yes.

Mr. HERMANN. I do not mean to interrupt.

Mr. WALDEN. That is fine.

Mr. HERMANN. But we are not a member of that council.

Mr. WALDEN. Were you ever a member of that council?

Mr. HERMANN. Sir, I am not aware of that, but I know we are not at this time.

Mr. WALDEN. Is Wes Signer of Patton Boggs ever represented Metabolife?

Mr. HERMANN. I am familiar with the name, but I am not familiar with that kind of detail of whose represented us from that standpoint, sir.

Mr. WALDEN. Okay. All right.

Well, I will give Dr. Boozer a moment here to look at the reviews. Because, among other things, the main points that were found, it was Dr. Atkinson, Esbalan and Hirsch and Kaplan, I think, were the 4 reviewers. And the main points from 3 reviews was that the formulation used in your study may not represent what is being marketed. And that, I think, is a question that is important. Was the product that was tested not actually out on the market?

Ms. BOOZER. Congressman, this was absolutely transparent in our publications. We published entirely the information about the product we were testing. There were 2 studies. In the one study we were studying Metabolife 356 and in the other study we made it absolutely clear that this was not a product that was on the market and we listed the ingredients.

Mr. WALDEN. And the ingredients are?

Ms. BOOZER. The ingredients are ephedra alkaloids and herbal caffeine.

Mr. WALDEN. Is that the combination they used in Denmark?

Ms. BOOZER. I believe they in Denmark, ephedrine, the synthetic version is used as a prescription compound in combination with caffeine.

Mr. WALDEN. Okay. And here?

Ms. BOOZER. We were using the herbal equivalent.

Mr. WALDEN. Okay.

Ms. BOOZER. We were using herbal ephedra and caffeine in the amounts of 90 milligrams per day of ephedra alkaloids and 192 of caffeine.

Mr. WALDEN. Okay.

Ms. BOOZER. That product—that combination, to my knowledge, is not available on the market. That was not our intention and we so clearly stated that in the publication.

Mr. WALDEN. All right.

Does that mean it does not demonstrate the efficacy of any ephedra supplement that is on the market?

Ms. BOOZER. As I say, to my knowledge there is no product on the market that has exactly that formulation. It was not the intent to study a specific product.

Mr. WALDEN. So the answer is it does not prove the efficacy of those that are on the market, correct?

Ms. BOOZER. I think it proves the efficacy of this combination for weight loss.

Mr. WALDEN. Okay. But what about what is on the market, because that is what consumers are really going into the stores and buying?

Ms. BOOZER. I think the Rand report summarized results from 52 clinical trials. And I think in their meta analysis they accounted for the variability, not every one of those trials had exactly the same formulation. But I would say judging from the summation of the review of those trials, it is fair to say that the combination of ephedra/caffeine is efficacious for weight loss.

Mr. WALDEN. Okay. Yes. What happens when you mix it up with these other ingredients? I mean, I have heard about an aspirin related product, it performs like that. And, you know, I have read ginseng and other things maybe mixed in. And I realize that may not have been part of your study, but from your experience and all can you speak to what effect that has, and the interactions?

Ms. BOOZER. Well, I think someone spoke this morning. We really do not know. We do not know what all of those individual ingredients or what they—we do not really know in total what they contribute or how they interact.

Mr. WALDEN. Okay. Are you aware of any of the studies that are out there on how ephedrine interacts or has been related to the problems with heatstroke?

Ms. BOOZER. No, I am not.

Mr. WALDEN. Okay. I would draw your attention to the last tab in the book from June 2003 Military Medicine where this was not an obese person, this was somebody who is very physically fit, well trained case study where he was on a run and had taken ephedra the night before and that day and suffered heatstroke related issues. And, in fact, the final conclusion here from the military is the risk of life threatening injury may outweigh any real or per-

ceived benefit of ephedra and clinicians and commanders should strongly discourage its use in active duty soldiers.

I also, when you get an opportunity to read the information from the Broward County, Florida Medical Examiner and Trauma Services Office, he also lays out, Mr. Preper lays out a number of studies and literature publications relating heatstroke and ephedra. So I would suggest for all the panel, since I have heard from most of you that there are no literature cites out there on that, that apparently there are. Obviously, I have not had a chance to read them and I am not a physician. But I would certainly draw your attention to them.

Mr. Chairman, I realize I have exhausted my time, and I appreciate the indulgence of the committee.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentleman from Illinois is recognized for 10 minutes.

Mr. RUSH. Thank you, Mr. Chairman.

Thanks to the witnesses for their patience.

Mr. Schreck, my first question is when were the words "heart attack and stroke" added to the label of your product and why?

Mr. SCHRECK. I believe that was a legal—I think that should be turned over to Mr. Hermann to answer, since he was here when that occurred.

Mr. RUSH. Mr. Hermann?

Mr. HERMANN. Yes, Congressman. The language on our label comes from a lot of different sources. Some of it from the Dietary Supplement Act in terms of specific things and follow up publications to that. But a lot of the warning language comes from—

Mr. RUSH. Let me be terribly specific here. I am referring to 3 words, "heart attack and stroke."

Mr. HERMANN. I do not know the date exactly, but those are required in the States of Ohio and Texas, and our label complies with that. Most recently California passed some additional labeling requirements and we have subsequently updated our label according to that.

As I recall, the Texas law and Ohio law were enacted since I have joined the company, but I do not specific—I'm sorry, Congressman. I will be more than happy to find out for you and I will get back to you on the answer.

Mr. RUSH. And my other question, which perhaps you will need to answer by supplementing the record, was did your company oppose those State legislatures that asked you to add those words to your label and if so, why?

Mr. HERMANN. I am sorry, Congressman, I do not know.

Mr. RUSH. Okay.

Mr. HERMANN. I will have to get back to you.

Mr. RUSH. This is a question for Dr. Colker. I want to refer you to Exhibit 31, and I am going to read a little quickly given the time constraints here. This is what appears to be an email from you to Bob Chinery, and the email, and I am just going to go ahead and read it very quickly. It is referring to 2 abstracts. And it says: "While the weight loss data are compelling, I would sense that with a full length paper we would have a lot of explaining to do." And then I am going to move the next line. "My first impression is the parameters are best enough left alone as they would have to be di-

vulged, explained in detail and scrutinized in a full length paper. So on this particular case we will gain from a marketing standpoint by relying on the abstract if it is accepted. On the other hand, we risk much exposure in full length form, just ask legal, on gaining nothing from a marketing standpoint.”

Now, have I accurately described a portion of this email?

Dr. COLKER. Yes, Congressman.

Mr. RUSH. Okay. Now this email was written in the context of your responsibilities to conduct what was supposed to be an independent scientific investigation, is that correct?

Dr. COLKER. That is correct, sir.

Mr. RUSH. Okay. I think you can understand why the email appears to us to comprise both the independent and scientific nature of your work, and I would like to give you the opportunity to explain that.

Dr. COLKER. Certainly. And I can understand how you come to that conclusion.

I felt I was being prudent when Mr. Chinery asked me whether this was a full length paper or whether a full length paper should be published. I felt it was more appropriate to give a snapshot of the primary endpoint, whether it was statistical significant difference between groups for weight loss and the other figures where—although there were absolute number differences between groups, they were not statistically significant and therefore, I would not want them to rely in their advertising on inclusive data.

Mr. RUSH. So what did you mean in the email when you said that “we will gain from a marketing standpoint by relying on the abstract if it is accepted and we risk much exposure if we use the full length form?”

Dr. COLKER. I felt from a marketing standpoint I was simply looking at it as looking out for Cytodyne in terms of feeling that was marketable information that was achieved from the study, while at the same time I felt that if there were any questions given the climate at the time, I referred him to legal.

Mr. RUSH. So it was your job to provide the independent scientific study or to provide advice and strategy on marketing?

Dr. COLKER. This particular study was an open label study. I felt it was certainly unbiased, but I can understand how one would read bias—

Mr. RUSH. So you were fulfilling both tasks? You were focusing on an independent scientific study and you were also providing advice on marketing?

Dr. COLKER. In this case, yes.

Mr. RUSH. And you do not find those to be inconsistent responsibilities?

Dr. COLKER. They were not for me, but I can understand how they might be viewed as such.

Mr. RUSH. Okay. Back to Mr. Schreck.

In 1998 Michael Ellis wrote a letter describing how the company handled consumer complaints, and I am going to paraphrase. He says Metabolife has a comprehensive safety monitoring procedures in place. We take the health of our potential and actual customers very seriously.

Our staff has reviewed your records and find them to be lacking in many respects, many were handwritten or illegible. The GAO has conducted a similar analysis and said the information in your call records was limited, sometimes difficult to understand and interpret. In some cases the evidence for report of an adverse event was limited to a single word on a call record.

I want to specifically refer to Exhibit 91 in the book in front of you. This is a notation on a day pad, dated September 21, 1998. It has the word "heart attack" written on it. And that's about all.

I want to ask you to comment on the quality of this record keeping in hindsight, and it is also a question directed to Mr. Hermann.

Mr. SCHRECK. I am sorry.

Mr. RUSH. I would like to ask you to comment on the quality of this record keeping with the benefit of hindsight and in view of the statement I read, assuming you don't object to my characterization of the statement from the Michael Ellis letter in 1998?

Mr. HERMANN. Congressman, if I could address that, I would be happy to answer your question.

Mr. RUSH. Please.

Mr. HERMANN. Our health information system was set up as a call center. As I said earlier, to help customers with questions that they had about how to use our product more effectively and questions about weight loss in general. It wasn't designed to capture adverse events. It was not formalized in terms of obtaining any information concerning any conditions or any reports. It was strictly used as a mechanism to do that.

As a dietary supplement company, as you know, we are not required to have a system in place for that. We do support the FDA in a proposal to implement that kind of system, and we are willing to work with the FDA to come up with a method and to identify what categories we should identify.

Mr. RUSH. Right.

Mr. HERMANN. I can only apologize for this particular record—

Mr. RUSH. You do not need to apologize to me. It is other people to apologize to, but go ahead.

Mr. HERMANN. Well, I am sorry, sir. I have lost the rest of your question.

Mr. RUSH. So it was not the intention of your record keeping process to record any adverse health events?

Mr. HERMANN. That is correct. The health information line was not set up to record adverse health events and we were not required to do that.

Mr. RUSH. Okay. I believe Mr. Chinery testified earlier that the policy of his company was to tell customers to take taking the product if they were experiencing adverse health effects. Was that the policy of your company?

Mr. HERMANN. Sir, I am not familiar with exactly what happened in any of these particular incidences. I do not—

Mr. RUSH. No, but I am not talking about a specific instance. You are the vice president of your company, right? I am asking you what the company policy was.

Mr. HERMANN. Congressman, the health information area does not report to me and it has never reported to me. I know that based on what I have seen is our policy, that if a customer does

call in, we ask them if they have talked to their personal physician—

Mr. RUSH. You were prepared for this testimony today, ostensibly by your lawyers, I'm sure. And you knew we were going to be asking about these questions, questions of this nature, and you cannot say as the vice president today or neither can Mr. Schreck as a representative what your company policy was on this particular point?

Mr. HERMANN. Congressman, I—you know, I can only tell you what I know. And I do not know the procedures or the policies at that time. And I am sorry. I just—

Mr. RUSH. Okay. Well, I would just like to ask you if you would supplement the record with that information.

Mr. HERMANN. Certainly, Congressman. Be more than happy to do that.

Mr. RUSH. In 1999 Allen Binky, or however you pronounce his last name, the counsel for Metabolife wrote to the FDA that your company has never been aware of any adverse health events by consumers of its product. Is that a correct statement, as you understand the record here? You have no reason to question that?

Mr. HERMANN. I haven't specifically seen—

Mr. RUSH. Well, let us assume I have stated correctly.

Based on your testimony I am assuming the reason your company was never aware of any adverse health events by consumers is you were not interested in collecting that information if any consumer called and tried to give it to you, is that correct?

Mr. HERMANN. Congressman, I am sorry, but I had nothing to do with that letter, with that phrase. I do not what the intent of those comments are. And I feel very uncomfortable speculating before this subcommittee on what it might have intended.

I can tell you this, in the 3½ years that I have been at Metabolife I have seen nothing but upstanding, honorable integrity. And I cannot believe that anybody would intentionally mislead the FDA or anybody else concerning our products.

Mr. RUSH. Well, understand. I am not suggesting anybody's intention or misleading. I am just asking what you thought was an appropriate policy or standard of care to adopt as a company in terms of collecting information from people that were calling you to report adverse health effects they were having that they were associating with the use of your product.

Mr. HERMANN. Yes, Congressman. I understand that. And I promise to get back to you with that information.

Mr. SCHRECK. Congressman, may I add?

Mr. RUSH. Yes, sir.

Mr. SCHRECK. Our company is being very proactive to improve our call system. We have hired Life Science Research Office to do an analysis so that we can assess our call centers and to take any recommendations that they will give us. This report will be completed early in the fall and I would forward it to you, if you would like.

And also I would like to state that we gave them no conditions and we put no conditions on the report. We asked them to do it of their own volition and they will—they are in the process of this

study at this point. And, as I said, we will have a report completed this fall.

Mr. RUSH. So when you printed on this label or your company for health questions and then a phone number, what were you intending to communicate to the consumers of your product as far as questions they could expect you to answer about health?

Mr. HERMANN. That particular phone number is the MedWatch number, I believe you are referring to. And that was required by Texas law, and that is when we implemented that on our label.

Mr. RUSH. I understand that is what the law required. But what did—okay.

Mr. HERMANN. I am sorry, Congressman. Were you referring to a different number?

Mr. RUSH. No, sir.

I have a document suggesting that your company has stated in the past that adverse event reports are only those reports which have proven to be casually connected to the product. Has that been the position of your company? Is that a fair statement?

Mr. HERMANN. I am sorry, sir. I don't—I am not familiar with that statement.

Mr. RUSH. Mr. Schreck?

Mr. SCHRECK. I am not either. I have never heard that before.

Mr. RUSH. How have the sales of your product fared since the negative publicity has arisen about their use? I will direct this to all three of you.

Mr. SCHRECK. The sales of our product have fallen.

Mr. GREENWOOD. Time of the gentleman has expired.

Mr. RUSH. Okay. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair at this point would like to call Ms. Culmo back to the witness table. Cynthia Culmo, if you would please come to the witness table and we will have a chair set for you. I wanted to—and I thank you for staying so long so that we could ask a few questions.

If you can use Mr. Schreck's microphone and, of course, you are still under oath.

Ms. Culmo, when you were at the Texas Department of Health did NVE, the company NVE ever come to your attention?

Ms. CULMO. Yes, they did.

Mr. GREENWOOD. And in what way and what actions were you involved with with regard to this company?

Ms. CULMO. To the best of my recollection their products became noticeable or to our attention in 1999. They were first reported on a poison control center report.

Mr. GREENWOOD. And were those adverse effects that were reported in the poison control report?

Ms. CULMO. That is correct.

Mr. GREENWOOD. Okay. And do you recall what kind of adverse effects you were seeing?

Ms. CULMO. Not off the top of my head, I do not.

Mr. GREENWOOD. Okay. And then did the department make contact with the company and make requests of the company or demands of the company?

Ms. CULMO. Yes, we did. We contacted the company to inform them that the name of their products were recognized street alternative drug names and that they would have to discontinue that name and also address other issues with the product.

Mr. GREENWOOD. And how did they respond to that?

Ms. CULMO. There are several records of correspondence. They, obviously, objected to that position.

Mr. GREENWOOD. Okay. Did they ultimately—was it a direct result of your demands that they change the name, that in fact they did?

Ms. CULMO. No. Actually what happened is our Attorney General's office was involved. And to the best of my recollection they agreed to no longer sell those products in the State of Texas under those names.

Mr. GREENWOOD. And so in a court supervised settlement?

Ms. CULMO. That is correct.

Mr. GREENWOOD. Okay. Thank you very much.

Ms. CULMO. I am sorry. I misunderstood that. There was an agreed order.

Mr. GREENWOOD. An agreed order?

Ms. CULMO. Yes.

Mr. GREENWOOD. An agreed order? Very well.

Mr. Occhifinto, do you agree Ms. Culmo's testimony? Use your microphone again, please, sir.

Mr. OCCHIFINTO. I do not remember any of the circumstances, all the circumstances. But I know that we came to an agreement with the State of Texas.

Mr. GREENWOOD. Okay. When you testified earlier in response to some questions that I asked and Ms. DeGette asked about what caused you to change the name of your products from Black Beauty and Yellow Jacket, you said that—I think you said that you had heard somewhere that over in Amsterdam products—repeat your testimony, if you will, as to what inspired you to change the name of the product.

Mr. OCCHIFINTO. We became aware of the product being used improperly on the Internet from a company in the Netherlands.

Mr. GREENWOOD. And when was that?

Mr. OCCHIFINTO. Within the last year, I believe.

Mr. GREENWOOD. Okay.

Mr. OCCHIFINTO. Within 6 months, maybe.

Mr. GREENWOOD. When did you agree pursuant to a court procedure to change the name of your product?

Mr. OCCHIFINTO. Chairman, I do not remember that as far—that was only for the State of Texas.

Mr. GREENWOOD. Right.

Mr. OCCHIFINTO. When we spoke before, I thought you meant in relevance to what was going on now.

Mr. GREENWOOD. So what you are saying is initially in 1999 the Texas Department of Health notified you that Black Beauty and Yellow Jacket were names for street illegal drugs and subsequent to that and a result of that you changed your marketing nomenclature in Texas?

Mr. OCCHIFINTO. Chairman, also on that list in Texas, they call those 2 names slang terms. They also use slang terms for drugs in

their State are Candy, Cakes, Cookies, Eggs, Squirrels, Biscuits, Beans, Truck Driver, Black Cadillacs.

Mr. GREENWOOD. Did you have any products with any of those names?

Mr. OCCHIFINTO. No, I did not.

Mr. GREENWOOD. Okay. So let us focus on the products you were marketing.

The Texas Department of Health informed you that your products Black Beauty and Yellow Jacket were street drug names?

Mr. OCCHIFINTO. Yes, sir.

Mr. GREENWOOD. Correct. Okay. And was that the first you learned of that or did you know that when you named them?

Mr. OCCHIFINTO. No, I did not.

Mr. GREENWOOD. You did not know that when you named them?

Mr. OCCHIFINTO. No.

Mr. GREENWOOD. Pure accident, coincidence?

Mr. OCCHIFINTO. No.

Mr. GREENWOOD. Okay.

Mr. OCCHIFINTO. I also tried to work things out with the Texas Department of Health and they were not cooperative. And then the Attorney General got involved in it and we came to an agreement and settled with them.

Mr. GREENWOOD. And what did you rename your products?

Mr. OCCHIFINTO. I renamed them for the State of Texas. Actually, I do not sell the products in any form in the State of Texas.

Mr. GREENWOOD. Okay. So when you changed—then you changed your nationwide marketing, you no longer call them nationwide, no longer call them, the product for instance Black Beauty?

Mr. OCCHIFINTO. No, I did not say that, Chairman. I said we no longer marketed those products in the State of Texas.

Mr. GREENWOOD. Okay. But eventually you stopped marketing Black Beauty entirely, correct?

Mr. OCCHIFINTO. Yes, we did.

Mr. GREENWOOD. Okay. And why did you do that? Why did you change its name?

Mr. OCCHIFINTO. Because we found that internationally people were selling our products as an illicit drug and we did not want to be involved in that. And we got out of the business and we changed the name.

Mr. GREENWOOD. So you wanted to have an entirely different kind of name for your product?

Mr. OCCHIFINTO. Yes.

Mr. GREENWOOD. So you changed Black Beauty to?

Mr. OCCHIFINTO. Midnight Stallion.

Mr. GREENWOOD. And that was to completely disassociate your product from Black Beauty?

Mr. OCCHIFINTO. Well, we were brought to the attention that Black Beauty was a name that people weren't comfortable with, so we stopped using that name.

Mr. GREENWOOD. Okay. Thank you.

Mr. Boozer, may I address some questions to you, please?

You do have a very impressive résumé. And let me ask you a question. What caused you to go into the field of obesity work? Why do you do what you do?

Ms. BOOZER. I think it was because of the opportunity to work with a very famous and excellent scientist named Dr. Joel Mayer, whom you may know. He had an outstanding reputation as an international nutritionist and obesity expert. And I had the opportunity to work with him at Harvard. And so, he was—because of his expertise in obesity, I got interested in working in that area.

Mr. GREENWOOD. Are you motivated, in part, by a desire to help people who are obese to not suffer the physical and emotion strains of their obesity?

Ms. BOOZER. That is right.

Mr. GREENWOOD. Okay. Do people sometimes individually ask you for advice as to how to deal with that very painful problem?

Ms. BOOZER. They do.

Mr. GREENWOOD. Okay. And what is your general recommendation if someone comes to you and says I am a 120 pounds overweight and I am miserable and I do not feel like I am healthy? What should I do, Dr. Boozer, to try to lose some weight and maintain that weight loss?

Ms. BOOZER. Well, as you know, I am not a physician so I don't give medical advice. But, in general, I think I would not hesitate to encourage everyone to eat a healthy diet which I consider to be a low fat diet.

Mr. GREENWOOD. Right.

Ms. BOOZER. And to increase exercise in their lives.

Mr. GREENWOOD. Right. And probably did not need to go to Harvard to learn that, did you?

Ms. BOOZER. No.

Mr. GREENWOOD. Okay. Because in fact, every doctor that I have ever heard of, and just about every expert, every trainer, they all basically say it comes down to limit your caloric intake, increase our exercise, advice like that. Okay.

So if someone came to you and you just told them you just testified that that's the kind of advice that you would give them, very sound advice, very mainstream advice. Would you say to them and take some ephedra or Xenadrine? Would you say this is another thing you ought to do?

Ms. BOOZER. No.

Mr. GREENWOOD. Okay. Why not?

Ms. BOOZER. Well, as I said, I have worked in a medical setting for many years as a nonphysician, and I am very conscious of the difference between my ability to give medical advice and that of the physician. So I would refer someone, and I have.

Mr. GREENWOOD. Well, you do not need a physician. I mean, the whole point of this hearing is that you do not need a physician to tell you to do this.

Ms. BOOZER. No, but—

Mr. GREENWOOD. You're qualified to suggest this. I am qualified to suggest this. The guy in the gym is qualified to suggest this. The guy at the minimart is qualified to suggest this, right?

Ms. BOOZER. Maybe so, but—

Mr. GREENWOOD. Well, you could walk into a gas station and say “fill her up with regular and, by the way, do you have any ideas of what I should do to lose this unsightly 50 pounds?” And the guy should say, sure, I got the product right here, right?

Ms. BOOZER. Right.

Mr. GREENWOOD. Okay. But you are an expert. But you would not recommend this product, would you?

Ms. BOOZER. As I say, I limit my advice to diet and exercise.

Mr. GREENWOOD. Right. But I am asking you a very serious question. This is a very important policy issue. Is the reason that you would not recommend this because you’re just not qualified and perhaps if you had a medical degree you would know when to recommend, or is the reason you do not recommend it is because you think it’s not a good idea for people to use this to solve their weight problems?

Ms. BOOZER. I have some of the same concerns that have been expressed earlier about the widespread use of these compounds. And while I feel that within the constraints of our study that people were not at risk, I still would have hesitation in advising people who are outside the constraints—such constraints to use this because it has not been widely studied.

Mr. GREENWOOD. Okay. So it has not been widely studied—

Ms. BOOZER. Under those conditions.

Mr. GREENWOOD. Right. Right. And you would not recommend it to anyone?

Ms. BOOZER. I would not recommend it, but—

Mr. GREENWOOD. Okay. And you, of all the people who have testified today in this long day of hearings, you are the obesity expert. You are the person who knows more about the problem that this product is designed to solve than anyone who has testified before this committee today. And your testimony under oath is that you would not recommend this product to anybody, is that correct?

Ms. BOOZER. Well, but as I said, I do not recommend products of any kind. My—I limit myself to diet and exercise.

Mr. GREENWOOD. But I thought we just went through this exercise where you said—I am not asking you if the reason you would not recommend this is because you do not have an MD after your name. I am asking you if the reason that you would not recommend this is because you do not see a good reason to recommend it because you think nutritional guidance, reduced caloric intake, more exercise is the better recommendation. And this has not been studied enough to know for you to feel confident about its efficacy and its safety.

Ms. BOOZER. Well, I mean I would not recommend it to someone without whom I had a lot of medical knowledge. For example, what their blood pressure was and what, you know—

Mr. GREENWOOD. And if you had all of that, you might recommend it, is that right?

Ms. BOOZER. It is possible. If I had someone that I was convinced met the same kind of conditions as the people who were in our study, then I might say to them, “Look, people like you who took this in our study did lose weight, did have improved blood lipids and without significant adverse event.”

Mr. GREENWOOD. Well, but that is—

Ms. BOOZER. But without—

Mr. GREENWOOD. It is one thing to say this had some impact for some people.

Ms. BOOZER. That is right.

Mr. GREENWOOD. It is another thing entirely to say this is what I would recommend. For instance, you could say some people lost weight eating pizza. Some people lost weight eating high fat foods. But I am asking you if you would recommend it.

Ms. BOOZER. Well, I personally would not, but that—I mean—

Mr. GREENWOOD. That is all I am asking you is you personally. That is all I am asking. I am not asking you on behalf of anyone else. You personally would not recommend the product.

Thank you. My time has expired.

Ms. DEGETTE. Dr. Boozer, in general there is concern among the research community about not just losing weight for obese individuals, but keeping that weight off over time, correct?

Ms. BOOZER. Very much so.

Ms. DEGETTE. And really the scientific evidence shows that nutrition and exercise are the two best ways to keep off weight long term, correct?

Ms. BOOZER. Well, having said that we know that that is extremely difficult.

Ms. DEGETTE. That is right.

Ms. BOOZER. Our success rate with obese population is on the order of 5 percent.

Ms. DEGETTE. Right. And fad diets, when people go on fad diets, for example, they help people lose weight in the short run but the studies show over the long run that among obese people that lose a substantial amount of weight on fad diets, do not keep it off, correct?

Ms. BOOZER. That is exactly right. That is right.

Ms. DEGETTE. Now, there were 2 studies done on ephedra. One by you, one was 8 weeks and one was 6 months, correct?

Ms. BOOZER. Right.

Ms. DEGETTE. So I think it would be safe to say that no study has been done to show the long term effect of weight loss in the population that you studied, which was admittedly a much smaller population than is taking this supplement. There is no evidence to show what the long term weight loss results are for those people, correct?

Ms. BOOZER. That is correct.

Ms. DEGETTE. Okay. I wanted to ask Dr. Colker, you said you were a physician and a sports trainer. Do you recommend that your patients take Xenadrine, your patients who athletes take Xenadrine?

Dr. COLKER. For some, Congresswoman, yes.

Ms. DEGETTE. Which ones?

Dr. COLKER. The ones that are—that have some weight to lose that I think that the benefits outweigh the risks.

Ms. DEGETTE. So you do not see any problem with athletes taking ephedra, correct?

Dr. COLKER. I think that I see no problem with athletes taking ephedra products, but I will say that my issues with athletes have

more to do with the abuse potential in general. I am not saying every athlete will abuse ephedra.

Ms. DEGETTE. Now, Mr. Chinery, I guess I would ask you, what is your company's policy toward marketing ephedra to athletes? Because on your bottle, which is right here, you say in a little box—I assume this is something else that was required by some State law, because it also has the same disclaimer on Metabolife. It says: "Keep out of the reach of children. Not for use or sale to individuals under 18." Right?

Mr. CHINERY. Yes.

Ms. DEGETTE. Now so you do not recommend it being sold to people under the age of 18, right?

Mr. CHINERY. That is correct.

Ms. DEGETTE. Do you have any way of stopping it from being sold to individuals under the age of 18?

Mr. CHINERY. Well, actually, I guess I should point out that we are not actually—we're not selling it anymore. But when we were—

Ms. DEGETTE. Oh, when you were. Thank you.

Mr. CHINERY. When we were selling it, a number of the major retailers such as WalMart and Target have a policy where they require identification for somebody to purchase it.

Ms. DEGETTE. What about for Xenadrine?

Mr. CHINERY. Yes.

Ms. DEGETTE. They required identification for that?

Mr. CHINERY. Yes.

Ms. DEGETTE. Did you have any written policies on that that you gave to your sales force?

Mr. CHINERY. I do not know that we had any written policy, no.

Ms. DEGETTE. Okay. So what was your policy regarding sales of this food supplement to athletes?

Mr. CHINERY. We did not have really a specific policy, but you know, there has been a number of clinical tests done on it and a majority of those did test it in conjunction with exercise. So—and I know that a number of other studies—

Ms. DEGETTE. So you think it is okay to sell it for athletes to use it?

Mr. CHINERY. As long as it is used properly by healthy individuals.

Ms. DEGETTE. Okay. Mr. Hermann, I think you said when I was questioning you it is your company's policy not to sell Metabolife to children or athletes, correct?

Mr. HERMANN. That is correct. We do not market it to children.

Ms. DEGETTE. You need to turn on your microphone. Thanks.

Mr. HERMANN. I am sorry, Congresswoman.

Ms. DEGETTE. That is okay.

After you said that, I was thinking about what Ms. Bechler said in the first panel and also Mr. Riggins about how they and their families know that Metabolife is sold at health clubs. So I was a little confused, because if it is your company's policy not to sell Metabolife to athletes, and you tell your sales force that, how is it being marketed then at health clubs?

Mr. HERMANN. Congresswoman, health clubs are not one of our retail outlets—

Mr. GREENWOOD. Your microphone still is not working.

Ms. DEGETTE. There. It is just not close enough.

Mr. HERMANN. Health clubs are not one of the retail outlets that we sell Metabolife to.

Ms. DEGETTE. Okay. So as far as you know, this is not being distributed from health clubs?

Mr. HERMANN. Not directly from us it is not, ma'am.

Ms. DEGETTE. Okay. Do you have any idea, Mr. Chinery, before you withdrew your product from the market, was it being marketed in health clubs?

Mr. CHINERY. I believe some, yes.

Ms. DEGETTE. Okay. And Mr. Occhifinto, is your product being marketed in health clubs?

Mr. OCCHIFINTO. We market for weight loss.

Mr. GREENWOOD. Please use the microphone, sir.

Mr. OCCHIFINTO. We market for weight loss products, and we market toward athletes.

Ms. DEGETTE. Okay. Do you think it is appropriate to use this supplement, your supplements for athletes?

Mr. OCCHIFINTO. I never explored that.

Ms. DEGETTE. So you have no opinion one way or the other?

Mr. OCCHIFINTO. No, I do not.

Ms. DEGETTE. Okay. I guess, one last thing, almost everybody here talked about the Rand study. And I was confused, because everybody here was saying that the Rand study supported their position, but I have a quote from the Rand study, and here is what it said. Please bear with me, but I think it is worth reading the whole quote.

"Overall, people who received ephedra or ephedrine had between 2.2 and 3.6 times higher odds of suffering harmful side effects, including psychiatric symptoms, jitteriness, palpitations, nausea and vomiting than did people taking a placebo. From the 284 reports of serious adverse events we identified 2 deaths, 3 heart attacks, 9 strokes, 3 seizures and 5 psychiatric cases as sentinel events with prior ephedra consumption. We identified 3 deaths, 2 heart attacks, 2 strokes, 1 seizure and 3 psychiatric cases as sentinel events with prior ephedra consumption. In aggregate, the case report suggests a link between products containing either ephedra and ephedrine and catastrophic events such as sudden death, heart attack, stroke, seizure and serious psychiatric symptoms.

Regarding safety we conclude from the clinical trials that ephedrine and ephedra are associated with 2 or 3 times the odds of experiencing psychiatric symptoms, autonomic symptoms, upper gastrointestinal symptoms and palpitations."

Do you agree with the Rand report findings? I will start, Ms. Culmo, I do not want to leave you out. Do you agree with those findings? We will just work our way down.

Ms. CULMO. Yes, that they are significant.

Ms. DEGETTE. Mr. Schreck?

Mr. SCHRECK. I do not agree with those. I think the Rand study also states that there were no serious adverse effects reports in the 52 clinical studies.

Ms. DEGETTE. Mr. Hermann?

Mr. HERMANN. I would support what Mr. Schreck said.

Ms. DEGETTE. Dr. Boozer?

Ms. BOOZER. Well, you know what I think the problem is, is there is sort—I think the report actually is quite good and I think they very carefully explain what they did, and it seemed consistent. But I think it is a little difficult when you read it like this to understand the difference between the control studies and the case report study.

In the control studies they looked at over 1700 individuals who had been studied and found no serious adverse event. And they conclude that those studies had an 80 percent power of detecting events at less than 1 in a 1,000.

So, in other words, they're saying that according to the clinical trials there is no serious adverse event unless this occurs at a rate of less than 1 per 1,0000 people. And the clinical cause cannot show that. So then they went to the case reports and they said now in the adverse event reports, and you read that. But they also go on to say however those do not show cause and effect.

Ms. DEGETTE. But the problem is that in the control study they did not look at the people who were high risk because those were not included in the studies of others.

Ms. BOOZER. That is exactly right.

Ms. DEGETTE. And what we are saying is the people who these terrible side effects happened to are the people who are taking this food supplement——

Ms. BOOZER. Absolutely.

Ms. DEGETTE [continuing]. Who are not in the control studies, right?

Ms. BOOZER. Absolutely. That is correct.

Ms. DEGETTE. Thank you.

I am out of time, Mr. Chairman, otherwise I would go down the rest of the panel.

Mr. GREENWOOD. The Chair thanks the gentlelady and at this moment would ask that without objection the document binders be introduced into the record. Without objection, so will be the case.

And the gentleman from Oregon is recognized for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman. I am sorry I had to step out for a moment.

Mr. Conklin, could you go to Tab 38 in the giant book here of documents? Is it true that you and Mr. Chinery were not pleased with the results that Dr. Armstrong reported for the RFA-1 study he performed?

Mr. CHINERY. I believe we not pleased the way he presented the results of the study in the abstract.

Mr. WALDEN. Okay. Is your email address or was it on 10 October 2000 kpconklin@aol.com?

Mr. CHINERY. Yes, sir.

Mr. WALDEN. Let me read an email of that date, 9:44:17 edt to tzphd@hotmail.com. Who is that?

Mr. CHINERY. That would be Dr. Tim Zigginfuss.

Mr. WALDEN. Got it. In part, and there are several things here but I will just cut to the part about Armstrong. It says "Armstrong study. I know you received the information from him and that you need it. Can you please wipe the quote/unquote shit off it and come up with something we can get published that will have impact. We

need this done asap. Let me know on this one.” What was that? What did you mean by all that?

Mr. CHINERY. Well, in hindsight, sir, I guess I could have used more appropriate wording to convey my thoughts to Armstrong to Dr. Zigginfuss. But what I had requested was that there was a lot of information that resulted from the study that was not included in the abstract that Dr. Armstrong first presented. So what we had liked to see was an abstract that included more information from the result of the study.

Mr. WALDEN. Okay. And would that explain the Wednesday, September 27, 2000 email Tab 36 from you to ttxphd@hotmail.com and you respond: “Okay. I sent you the study results from Astrong” you say. “Could you please try to find something positive from this, something we can salvage. Could this possibly be a safety study. Let me know, please. This is screwed. K” What was that about?

Mr. CHINERY. What had happened was Dr. Armstrong completed, we will say part of the study. He did not stick to protocol that we agreed on prior to the study commencing. And the results, we will say it was partial results of the study. I am not a research doctor or scientist, so I really could not interpret the data. And what I had asked Dr. Zigginfuss to do was to look at that and interpret it for us and he had come back with positive results from the study at that point.

Mr. WALDEN. Is Tim Zigginfuss a paid consultant by Cytodyne?

Mr. CHINERY. He was, yes.

Mr. WALDEN. Was he during this period in 2000?

Mr. CHINERY. I cannot be sure, sir.

Mr. WALDEN. Mr. Chinery, you are president of the company?

Mr. CHINERY. I believe he was a consultant. And, actually, he was hired to consult on having research projects commissioned for Cytodyne products. So I believe he was at that point.

Mr. WALDEN. Okay. If we could go to Tab 38. Mr. Zigginfuss. Yes, this is from Mr. Zigginfuss. Am I saying that right, Zigginfuss?

Mr. CHINERY. Yes.

Mr. WALDEN. Okay. Thursday, November 9, 2000, 2:32 p.m. to Bob C. at prosourconline.com and cc to Mr. Conklin, subject EMUXN study. He writes: “Hello, guys. Just thought you might want to hear my interpretation” in all caps, “of the EMU study. Dr. Armstrong sent me the entire report with all the numbers and it looks much better than any of us expected and particularly what he originally communicated to Kelly. For instance, I know using percentages can be misleading (especially when the absolute changes are small) but check this out.” And then he says body weight change and goes through that, and the placebo and fat mass change and placebo.

And then, quoting again, “And these effects occurred despite no statistically quote/unquote significant changes in either groups dietary intake. However, if you look at actual numbers as the placebo group actually reduced their total calorie intake by 200”—it is hard to read this—“per day and their fat intake by”—I think it is 30 but it is hard to read this printed copy—“grams per day from pre to post testing. Had not this happened the above changes would have been even more dramatic. Damn I am good.”

The body change weight was small, correct? The actual loss of weight?

Mr. CHINERY. I guess that would be subject to individual interpretation.

Mr. WALDEN. Is 3.19 pounds body weight change small for the placebo?

Mr. CHINERY. Well, I think if you look at it in the full context these people did not reduce their diets and they lost weight, a significant weight, it was deemed to be statistically significant. So therefore, I do not know that I would agree that it is small.

Mr. WALDEN. Okay. But in the email he uses the percentage, and I did not read this earlier, that 759 percent more weight loss than in the Xene group. 3.9 pounds versus 759 percent. And then under the fat mass change placebo versus Xene, that is 524 percent more fat loss in the Xene group. And you are talking 5.7 pounds.

Why were those percentages important to your company, and did you use them in any of your marketing?

Mr. CHINERY. I am not positive whether they were used in marketing or not, but typically in this industry the products that are advertised to a certain segment of the market, which is the fitness market, that that is the way those types of results are typically expressed.

Mr. WALDEN. You said you did not know whether these numbers were used in your marketing, correct?

Mr. CHINERY. I cannot be positive.

Mr. WALDEN. Well, did not the judge in the Park case find that these percentage changes were misleading? Are you familiar with the Park case?

Mr. CHINERY. Yes, I am. Specific to both of these percentages claims, I am not sure. I know that—

Mr. WALDEN. What about other percentages claims, were they similar to these in terms of percentage versus the numbers?

Mr. CHINERY. I think there was a lot of variability with regard to the actual changes that took place between the 2 groups.

Mr. WALDEN. What does that mean?

Mr. CHINERY. Well, there were other percentage claims used in other advertising. And—

Mr. WALDEN. But were you not really talking about a couple of pounds? I will give you 3 to 8 pounds, but then claimed that the difference was hundreds of percent? Did you ever use any of that in your advertising, 100 percent claims or more?

Mr. CHINERY. Percentage claims, yes.

Mr. WALDEN. Was 1700 percent difference a claim used?

Mr. CHINERY. Yes, it was.

Mr. WALDEN. And how much weight difference was that?

Mr. CHINERY. I believe that claim was specific not to body weight, but body fat.

Mr. WALDEN. Okay. Give me the number.

Mr. CHINERY. I do not have that number off the top of my head, but I know it was a very high—

Mr. WALDEN. Does counsel have that number? Did they defend you in that case?

Mr. CHINERY. That was different counsel.

Mr. WALDEN. Was 3860 percent used by your company?

Mr. CHINERY. Yes, it was.

Mr. WALDEN. Was that found to be misleading in the Park case?

Mr. CHINERY. In that case it was, and in another case in Federal court in Utah it was found to be supported by the study and appropriate.

Mr. WALDEN. Okay. In either case how much—was this body weight or fat, or what was it?

Mr. CHINERY. Again, that was actually body fat.

Mr. WALDEN. And what was the actual number?

Mr. CHINERY. I do not have the specific number, but again the difference between the 2 groups was a very high statistical significance in that study.

Mr. WALDEN. Do you think the difference of a couple of pounds here is very high statistical significance?

Mr. CHINERY. Well, it is considered a powerful number by the people that review the study and the people that do the statistics.

Mr. WALDEN. Who paid for this study?

Mr. CHINERY. The study that we are looking at here, this Eastern Michigan study?

Mr. WALDEN. The Armstrong?

Mr. CHINERY. Yes, that was actually paid, Cytodyne provided a grant to Phoenix Laboratories which then provided that to the university.

Mr. WALDEN. Yes. Okay. Dr. Zigginfuss says “and these effects occurred despite no statistically significant changes in either groups dietary intake.” So neither group changed their dietary intake at all?

Mr. CHINERY. I believe the protocol of that study called for no changes to dietary habits.

Mr. WALDEN. Yes. How long was that study?

Mr. CHINERY. I believe that was a 6 week study.

Mr. WALDEN. Six weeks?

Mr. CHINERY. Yes.

Mr. WALDEN. Okay. So in 6 weeks the difference between the 2, if I am reading this correctly, is about a little less than 2 pounds—a little over 2 pounds, 2½ pound difference between the placebo group. Is that right? Am I reading this right?

Mr. CHINERY. With regard to body weight, but I think it is also important to look at fat mass change, because ultimately that is what most people are interested in losing. And that number is—the differential between those two groups is much higher there.

Mr. WALDEN. What is that number?

Mr. CHINERY. It is 5.7 pounds from using Xenadrine without dietary restrictions versus 1.08 pounds with the placebo.

Mr. WALDEN. So roughly a 4 pound difference in 6 weeks between the two?

Mr. CHINERY. A little more than four.

Mr. WALDEN. And from that you tell consumers in effect, or it was being suggested you could, I guess, have 524 percent more fat loss in the Xene group? And you are comfortable saying that to consumers?

Mr. CHINERY. Well, you know, it is a pretty significant number and it was statistically significant, and it was eventually accepted for publication.

Mr. WALDEN. Okay. This Tab 39 also has an "hey Bob" email. Also from Tim. It says "Thanks for the message. I originally thought the same thing and that Armstrong run a comparison on lean mass changes BT groups. Unfortunately, both groups increased lean mass from pre to post testing and although the increase in the Xene group was 161 percent greater than the increase in the placebo group, the diffs were not quote/unquote statistically significant. Probably due to variance in response. However, my opinion the effect does warrant mentioning in the full paper." I mean, there he is saying on lean mass it is not statistically significant even though 161 percent difference.

Mr. CHINERY. Correct.

Mr. WALDEN. Yes.

Mr. GREENWOOD. The time of the gentleman has expired.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman from Illinois is recognized for 10 minutes.

Mr. RUSH. Thank you, Mr. Chairman.

I would like to go back to Mr. Schreck. Earlier, as perhaps you heard, Mr. Vasquez testified that he was instructed in phone calls not to use the term side effects. Can you or Mr. Hermann comment on what policy or practice might have been in place at the company that would have led him to make that statement?

Mr. HERMANN. No, Congressman, I am sorry. I am not familiar with that. I do not know why that statement was made, but we will get back to you on those policies, sir.

Mr. RUSH. Mr. Schreck?

Mr. SCHRECK. I feel the same way. I was not part of the company then. I had not heard that statement until this morning, and as I have mentioned earlier, we believe in consumer protections and I do not know where this statement emanated from or why.

Mr. RUSH. Okay. Ms. Culmo, earlier I asked a question I would like to direct to you, since you have just recently joined the panel, and it was when were the words "heart attack and stroke" added to the label of this product and why if you can respond to that?

Ms. CULMO. Yes, sir. The Texas Department of Health enacted regulations that went into effect in November 1999 that required that warning that did in fact include heart attack and stroke. And I think there your subsequent question to that was did Metabolife oppose that. And, yes, they did. They are on record with that opposition.

Mr. RUSH. Can you say what the record reflected as far as the basis for their opposition?

Ms. CULMO. It was pursuant to what we call a public docket at the Texas Department of Health. It includes all the adverse event reports that we had received, physicians reports published, articles, medical journal. Two medical scientific panel reviews of the docket.

Mr. RUSH. What was the gist of the basis for their opposition, if you recall?

Ms. CULMO. The discussions were based around the fact that it would be detrimental to sales to put something like that on the label and that there was not adequate evidence to support that warning.

Mr. RUSH. Would either you gentlemen care to comment on this point? Do you understand that to be an accurate description of the position of the company with respect to this Texas regulation?

Mr. HERMANN. I am sorry, sir, that was before I joined the company. I have no information about that.

Mr. SCHRECK. And I was not involved with the company at that time. And have no knowledge of what happened in Texas at that time.

Mr. RUSH. You all do have knowledge about what happened at the company before you joined it, I assume?

Mr. SCHRECK. We do have some knowledge.

Mr. HERMANN. Some knowledge, yes.

Mr. RUSH. Okay. Ms. Culmo, I believe there has been a statement made earlier about Metabolife, I do not know who made this statement, that the development of their product was similar to—and my terminology is going to be weak here—that the process that they followed to develop their product was similar to the standards that would be followed in developing similar products under the OTC monograph. Perhaps you can state my question more competently than I did and then you can respond?

Ms. CULMO. Yes. There were a couple of points made by some of the panel members that I did in fact believe warranted some clarification. And one of those was the referral to the OTC, over-the-counter monograph of dialators and decongestants. That is something that the industry basis the safety of their products on. I think the clarification needs to be made that that monograph was pursuant—it addresses a very specific subpopulation within the general population; that is those persons that have been diagnosed, medically diagnosed with asthma that are to take those drug products at those recommended doses.

It also has a warning in there that if the first dose is not effective, within 5 minutes you are to call your medical practitioner. It is uncommon that someone would breach the maximum dosage that's in that monograph.

The other thing that I think is very important for people to know is that ephedrine never had safety or efficacy studies done. They were grandfathered into that monograph.

Mr. RUSH. Okay. Would anybody on the panel like to comment on this last particular point? Okay.

I am aware of a study done by Haller & Benowitz in December 2000 published in the New England Journal of Medicine which examines the effects of ephedra based products on Marines at Camp Pendleton. Is anyone on the panel familiar with that study? Has anyone read that report in the New England Journal of Medicine? Has anybody heard about the report? Is somebody nodding their head? The record cannot reflect—Dr. Colker, if you can say.

Dr. COLKER. I recall reading it, but I really—the details escape me.

Mr. RUSH. Well, let me describe to you—

Dr. COLKER. Help me with the question.

Mr. RUSH. Let me describe to you what I think it said, and for purposes of my question you can assume I am being accurate.

The study was based on the survey and medical data from the First Marine Division at Camp Pendleton and found that 7 percent

of Marines reported daily use of ephedra in dietary supplements during the year 2000, and half of the Marines with heat related injuries in 2000 in that division had used ephedra. That is a pretty significant statistic, and I would like to give you the chance to comment or anyone else on the panel that would care to do so.

Dr. COLKER. The way it is written, Congressman, it certainly sounds very significant and I do not have any other response other than to say from what I recall in general about the study, it was an observational—it was observational data and it was anecdotal data. I do not think it was a structured study in anyway. And, thus, I think there is a difference.

Mr. RUSH. Anyone else care to comment on that? Okay.

A question to anyone on the panel who cares to answer it. How effective had the State laws to date in New York, Illinois, perhaps other States, been in protecting those individuals under 18 from buying the ephedra product?

Ms. CULMO. Congressman?

Mr. RUSH. Yes, ma'am?

Ms. CULMO. I cannot comment on that. There are State surveys that are published in public dockets where they have done undercover buys for these products. And they are easily accessible, and so quite frequently to persons under the age of 18.

Mr. RUSH. Okay. Now, certain sporting groups, baseball and others, have banned the use of ephedra products. Is that correct? Can someone comment on what the basis was for the decision to institute that ban?

Mr. HERMANN. Congressman, I am not aware of what their basis was, but we are on record of not supporting the use of ephedra products for athletic enhancement.

Mr. RUSH. So you support that ban?

Mr. HERMANN. Yes, we do, Congressman.

Mr. RUSH. Okay. Comments from either of the other principles of the companies? You support the ban as well, if you have a position?

Mr. OCCHIFINTO. Congressman, I do not offer my products for the sports—

Mr. GREENWOOD. Bring your microphone to you.

Mr. RUSH. You do not offer your products?

Mr. OCCHIFINTO. I do not offer my products into that marketplace.

Mr. RUSH. Okay. Thank you, Mr. Chairman. Thank you.

Mr. GREENWOOD. Ms. Culmo, you seem to be trying to get my attention?

Ms. CULMO. Yes, sir, if I may, there was one more point I would like to clarify.

Mr. GREENWOOD. Please do.

Ms. CULMO. And there has been references to our comparison of the statistics for aspirin and acetaminophen to poison control centers and its numbers. I would like to point out that one more time, specific comparison of a dietary supplements to a drug product, those drug products are on the market on a completely different standards and evaluations. And if in fact they want to compare the products, dietary supplements or foods to a drug statistics, then

they should be on the market in the same manner in which those drugs are made and available.

Mr. GREENWOOD. Thank you, Mr. Culmo.

The Chair would inform all of the members of the subcommittee and the witnesses that this hearing will be over before 7, at the latest. I know probably many of you are eager to complete your travel plans.

Let me ask Mr. Schreck a question. I am looking at your Metabolife 356 container and various ingredients. One of them that I find intriguing is that it contains royal jelly. Could you tell us what royal jelly is?

Mr. SCHRECK. I will have to pass that to Mr. Hermann since he is involved in the production of the product.

Mr. GREENWOOD. Mr. Hermann, what is royal jelly?

Mr. HERMANN. I am sorry, Chairman. I really do not know what royal jelly is.

Mr. GREENWOOD. You are in charge of making the product?

Mr. HERMANN. Yes, Chairman, I am. But I——

Mr. GREENWOOD. It seems to me then you would be in charge of making sure that the royal jelly that gets in here is good royal jelly and that the right amount of royal jelly gets in here, not too much, not too little. Would that not be right?

Mr. HERMANN. Absolutely, Chairman. And we do make sure that the ingredients according to the formula are in the product.

Mr. GREENWOOD. So you can testify that only pure and clean royal jelly gets in this product and that too much of it and not too little gets into the product, is that correct?

Mr. HERMANN. We set specifications for all the raw materials that go into——

Mr. GREENWOOD. But you cannot tell me what royal jelly is?

Mr. HERMANN. I do not have personal knowledge about what that is, sir.

Mr. GREENWOOD. That is very interesting.

And who in your company could tell us what royal jelly is?

Mr. HERMANN. One of our chemists or the gentleman in charge of research and development at our laboratory.

Mr. GREENWOOD. What is bovine complex?

Mr. HERMANN. That is a complex that came from cattle.

Mr. GREENWOOD. Okay. Do you know what part of the cow it comes from?

Mr. HERMANN. Not specifically, no sir, I do not.

Mr. GREENWOOD. But you are in charge of making sure that whatever piece of a cow goes into this capsule is good for people, not bad for people, right?

Mr. HERMANN. Congressman, I am in charge of manufacturing the product according to the requirements of our formula and making sure that we follow that formula——

Mr. GREENWOOD. Okay. So when——

Mr. HERMANN [continuing]. Other than that the company will discern whether or not those products are——

Mr. GREENWOOD [continuing]. You make sure that the right amount of bovine complex gets in here, how do you do that?

Mr. HERMANN. Through various analytical methods, sir.

Mr. GREENWOOD. Okay. So when you're analyzing your bovine complex, how do you analyze your bovine complex?

Mr. HERMANN. Sir, I am not a scientist. I do not know the process that is taken to do that. However, we do have batch records that support analysis of our product throughout the entire system. We do not just make one test. We test raw materials when they come into our facility to make sure they meet our specifications and then in every step through the manufacturing process we will pull samples. Once it is mixed and before it is tableted, and then after it is tableted to make sure that it does—that the ingredients that are listed on the label are in the product in accordance with what the label says is in the product, sir.

Mr. GREENWOOD. So all you know is that some barrels of stuff come in that say bovine complex and you know how many grams or ounces or pounds or what of bovine complex goes into a batch of Metabolife, but you have no clue as to what—whether that's cow ears, nose, throats, brain, testicles? You do not know what part of the cow goes into this thing?

Mr. HERMANN. Sir, not myself personally. I have people that report to me who do have the specialties and do know that.

The bovine complex, I do believe—well, I do know this: It is no longer in our product. It was removed from the product.

Mr. GREENWOOD. Do you know why that is?

Mr. HERMANN. Pardon me?

Mr. GREENWOOD. Do you know why you removed the bovine complex?

Mr. HERMANN. It was removed from the product about a year ago, about the same time when all the publicity on Mad Cow Disease in Europe. We felt that it was—after reviewing the formula with various scientists, we determined that it could be removed from the product without changing performances of the formula.

Mr. GREENWOOD. That's funny. Then one would wonder why it went in to begin with.

Mr. HERMANN. I do not know that, sir.

Mr. GREENWOOD. Do not know that either. Okay.

I would appreciate it if you would have your scientists inform the committee as to what royal jelly is and what constituted the bovine complex that you used to put in the product.

Mr. HERMANN. We would be more than happy to do that.

Mr. GREENWOOD. Thank you.

Mr. Occhifinto, I am going to return to you?

Is it Occhifinto or Occhifinto?

Mr. OCCHIFINTO. Occhifinto.

Mr. GREENWOOD. Occhifinto. And you will need to pull your microphone.

You stated in your June 5, 2003 letter to the committee that Stacker 2 Lite has less ephedra than other of your products, is that not right?

Mr. OCCHIFINTO. Yes.

Mr. GREENWOOD. Okay. You also agree that your various ephedra-containing products such as Yellow Jackets or Yellow Swarm, Black Beauty, Stacker 2, Midnight Stallion have other active ingredients besides ephedrine and caffeine? They have other active ingredients?

Mr. OCCHIFINTO. There is other herbs in those products. I do not know whether you would consider them active ingredients. There are other herbs in those formulations.

Mr. GREENWOOD. Okay. And can you tell us what some of them are?

Mr. OCCHIFINTO. There is—I believe there's maybe ginseng in some of those formulas, green tea, cola nut. That is all I remember off hand.

Mr. GREENWOOD. I thought you were the developer of the formula?

Mr. OCCHIFINTO. I am the developer of the formula, but they have been developed over the years. I do not remember every ingredient and why I put it in there when we did the development work on it.

Mr. GREENWOOD. Really? Is bitter orange, citrus aurantium, is that in the product?

Mr. OCCHIFINTO. Yes, I believe it is in maybe 1 or 2 of those products.

Mr. GREENWOOD. Okay. And what made you decide you wanted to put that in there?

Mr. OCCHIFINTO. It was a popular supplement that was coming out to replace ephedra on the market a couple of years ago.

Mr. GREENWOOD. Okay. Is it a stimulant?

Mr. OCCHIFINTO. I believe so.

Mr. GREENWOOD. Is it standardized for ceneffrene, which is a stimulant?

Mr. OCCHIFINTO. I am not sure of the pharmacological—what it pharmacologically does and what I have read about it, I believe it is a slight stimulant.

Mr. GREENWOOD. Ms. Culmo, do you know what citrus aurantium, bitter orange does, what the impact of that is?

Ms. CULMO. Yes.

Mr. GREENWOOD. Could you tell us?

Ms. CULMO. Citrus aurantium also contains the active ingredient epinephrine. It is the one that Dr. Woosley alluded to earlier that it is believed also has cardiac stimulant activity.

Mr. GREENWOOD. Okay. And can you comment on what you think the impact of that would be to combine that with ephedrine and perhaps caffeine?

Ms. CULMO. Well, the concern has been anytime you combine these stimulants, you obviously are going to have an increased effect of all of them.

Mr. GREENWOOD. An added effect, cumulative effect of more than one stimulant?

Ms. CULMO. Definitely.

Mr. GREENWOOD. Okay. Thank you.

Back to you, Mr. Occhifinto. All your products do not have the same exact formulation, do they?

Mr. OCCHIFINTO. No, they do not.

Mr. GREENWOOD. Okay. For example, your Stacker 2 product is not formulated identical to Black Beauty, which is now known as Midnight Stallion and Black Beauty/Midnight Stallion did not have the same amount of ephedra and caffeine as Yellow Jacket or Yellow Swarm do, is that right?

Mr. OCCHIFINTO. Congressman, I did not hear the last part of the question.

Mr. GREENWOOD. I am saying that your different products, Stacker 2 has a different amount of ephedra than does Midnight Stallion, and that is different than Yellow Jackets or Yellow Swarm?

Mr. OCCHIFINTO. I believe at this time that most, except for our Stacker Lite product and figure free products have the same amount of ephedra in the formulas.

Mr. GREENWOOD. As of when? You say "now you think they are the same?" Because I am aware that we have consumer complaints that were sent to your company that lists Black Beauty as having 25 milligrams of ephedra and 200 milligrams of caffeine per pill, Yellow Jackets 30 milligrams of ephedra 300 milligrams of caffeine per pill. So was that the case before you changed? Did they have different dosages?

Mr. OCCHIFINTO. I do not know what you are referencing there. Most of our formulas were for 25 milligrams—equivalent to 25 milligrams from the ephedra source. Or if it was Stacker Lite, it was 1½ milligrams of ephedrine.

Mr. GREENWOOD. But you never intentionally had different levels of ephedra for a different level for Black Stallion than for Yellow Swarm, or whatever it is?

Mr. OCCHIFINTO. We have been in this business for a long time. The formulas have changed from time-to-time to meet different requirements for different States. I do not know which formulas you are referring to. I know that most of ours are standardized to 25 milligrams ephedrine, and the amounts of caffeine or what usually varies.

Mr. GREENWOOD. What is your understanding of the OTC monograph concerning the maximum amount of ephedrine and caffeine that a person should ingest during a 24 hour period?

Mr. OCCHIFINTO. I do not know what the maximum is of caffeine, but I believe it's 160 milligrams of ephedra.

Mr. GREENWOOD. Is the maximum that a person should ingest in a day?

Mr. OCCHIFINTO. I believe so.

Mr. GREENWOOD. Okay. I just want to go back to one point that we were discussing earlier. When I asked you about documentation of your formula, virtually none of which you have supplied to this committee, you said well we supplied the formula cards. Okay.

The question that I was really trying to get at is documents that would educate us as to what process you went through in developing the formula. In other words, are there no documents in your company that would represent a description of how your company came to choose the particular formulas that it ultimately uses?

Mr. OCCHIFINTO. That is true, Congressman.

Mr. GREENWOOD. And how would that be? It just came straight out of your head?

Mr. OCCHIFINTO. The formulas were developed by referencing herbal books, magazines, what was on the market, what could be sold and how the product would work after it was formulated.

Mr. GREENWOOD. Okay. So you used these references and then told your company to manufacture per these specifications and just

handed them a book or handed them a magazine article? Is that how you did it?

Mr. OCCHIFINTO. No. Extrapolated that information and wrote formula cards that are followed to make sure that the product got——

Mr. GREENWOOD. So you went straight from the reference to the formula card without any other intervening documents or paperwork that you——

Mr. OCCHIFINTO. There really was nothing generated for that.

Mr. GREENWOOD. Okay.

Mr. OCCHIFINTO. We really went straight from there and formulated the products.

Mr. GREENWOOD. Okay. Can you tell us, what reference would you have used to formulate Yellow Jacket, for instance? And yet what is now called Yellow Swarm. Where did you turn to find that formula?

Mr. OCCHIFINTO. Well, the formula for the ephedra and the caffeine is pretty much standard in the industry, not to go over 26 milligrams of ephedrine. Now the rest of the components in it we are just using research documents. We have a library of herbal books and just look through those books to find complimentary herbs.

Mr. GREENWOOD. Okay. When you renamed Yellow Jacket to Yellow Swarm, you increased the ephedrine and you added another ingredient, correct?

Mr. OCCHIFINTO. Chairman, I do not remember what the other ingredient that I added to it. If you are talking about an—we increased the ephedra 10 milligrams, which would be the equivalent of one milligram of ephedra in it. And the only reason we did that is to standardize our formulas so they all were 25 milligrams of ephedrine.

Mr. GREENWOOD. Okay. Did you take out citrus aurantium at that time?

Mr. OCCHIFINTO. I do not recall.

Mr. GREENWOOD. Okay. There is a stunning lack of information among some of you on this panel as to what is contained in the products you sell.

The Chair recognizes the gentlelady from Colorado.

Ms. DEGETTE. Mr. Chairman, I have no further questions.

I would like to thank you for holding this hearing and say how much I look forward to the hearing tomorrow. And also to note that I share your extreme concern over the fact that people are marketing what are called dietary supplements which are clearly having an adverse health effect on Americans and which are not, apparently, controlled in any way.

And furthermore, how we have a bunch of people in this industry, this is only one product, ephedra. And we have a bunch of people who are making pills they do not even know what is in them, they do not have Ph.D, like Dr. Boozer, they do not have even college degrees. And I think that this is an area—I know from my own personal experience that my friends are increasingly interested in herbal supplements. I think this is an area that this committee has to put continuing attention to. And I am really inter-

ested to hear what the regulators say tomorrow. So thank you for holding this hearing.

Mr. GREENWOOD. Thank the gentlelady for her many hours of participation.

The gentleman from Oregon is recognized for 10 minutes.

Mr. WALDEN. Thank you very much, Mr. Chairman.

Mr. Conklin, when you approached Dr. Armstrong about speaking out on behalf of your product, what was his response?

Mr. CONKLIN. I am sorry, sir. Could you please repeat that?

Mr. WALDEN. I am sorry. When you approached Dr. Armstrong about speaking out on behalf of your product, what was his response?

Mr. CONKLIN. At first he was hesitant. He said he was not good in front of a camera.

Mr. WALDEN. Would you say he was cooperative in nature but just hesitant?

Mr. CONKLIN. He eventually became cooperative, but he was hesitant because he was, we will call it camera shy.

Mr. WALDEN. So it was camera shy, it was not about not wanting to be associated with the percentage claims versus the actual number claims?

Mr. CONKLIN. Well, the initial comments from him were that he is not good in front of a camera.

Mr. WALDEN. Initial comments? Did he ever express to you any hesitation about the use of percentages in the advertising?

Mr. CONKLIN. Yes, sir, he did. Initially as I have seen with various scientists and research scientists, they do not like to express anything in percentages or in any other means. They are very scientific and they stay away from anything that has to do with advertising.

Mr. WALDEN. Is not Dr. Zigginfuss a scientist?

Mr. CONKLIN. He is a research scientist, yes.

Mr. WALDEN. He seems to be a real advocate for using these percentages, is he not?

Mr. CONKLIN. Well, there are some that are. There are some that are not.

Mr. WALDEN. Yes. But he was actually more in your marketing side of promoting this than the research side, is that right as a consultant?

Mr. CONKLIN. Well, he was hired as a consultant to contract other research institutions to do studies on Xenadrine.

Mr. WALDEN. Well, was he not also trying to nudge Dr. Armstrong to come out with the right data in the abstracts and how he used the data?

Mr. CONKLIN. Well, that would not be accurate. He was—Dr. Armstrong, though the data existed, did not present that data. So Dr. Zigginfuss spoke with him in order to get him to present the data that was obtained from the study.

Mr. WALDEN. Or present it in a way that would be more favorable for marketing purposes?

Mr. CONKLIN. Well, I mean, the results were such that, you know if a statistician were to I guess work on them mathematically the percentages would be correct. And I guess through his discussions

with Dr. Armstrong they both came to that conclusion or Dr. Armstrong came to that conclusion.

Mr. WALDEN. Okay. Regarding the advertising, what role do you play in the advertising?

Mr. CONKLIN. My role is to work with athletes and/or celebrities who endorse the product.

Mr. WALDEN. Okay. And do you then actually produce the ads, do you write the scripts, do you hire the production firm? How does all that—do you play a role in all of that?

Mr. CONKLIN. No, sir, I do not.

Mr. WALDEN. You do not? So you do not line up people to speak on camera and that sort of thing?

Mr. CONKLIN. I do not do what?

Mr. WALDEN. Line up people to speak on camera? You do not make those decisions or recommendations of who should be on camera, who should not in your advertising, the marketing?

Mr. CONKLIN. Well, if we have plans where we going to do someone for a commercial or something like that, then I would look for people who have achieved success with the product or celebrities or athletes to go on a commercial or we will say in front of the camera.

Mr. WALDEN. Okay. Because I was just looking at an email that you had sent to Bob C, Tab 43. It sure sounds like when I have done ads, kind of the person that produces them. "Armstrong was not being cooperative as far as interviews or locating test subjects. I finally talked him into giving a one liner off camera that can be worked into the VNR as a quote from the author. We can than—" although I know you mean then—"include interviews from Zig, Calman and/or Colker. Zig can use the angle that he has reviewed several studies and this one kicks ass. You get the point. Colker and Calman can use the angle that this study yielded—" and it goes on and on and on.

To me that sounds like you are kind of scripting out how to do the ad. It is not a bad thing. I am just trying to figure out what your role is.

Mr. CONKLIN. Well I guess my role could be putting projects together. And in this case, it was a video news release of VNR.

Mr. WALDEN. Yes.

Mr. CONKLIN. And I was——

Mr. WALDEN. So this was a new release trying to work the press on the results. Is that what a VNR is?

Mr. CONKLIN. Right. Correct. Yes.

Mr. WALDEN. Okay. Go to Tab 5 if you would, and there is an email from Kelly Conklin to John Jay Murphy, dated November 19, 2002.

"John, thanks for the kind words. I left there with a good impression of you. Also I have a training video that we may be doing in the near future, may want to include you. Can you get ripped in case this thing goes through in a couple of weeks? If it does not, no harm done." What is "ripped?"

Mr. CONKLIN. Well, that is a common term used amongst athletes to show muscularity, low body fat.

Mr. WALDEN. Okay. And why would you tell him to get ripped in case this thing goes through in a couple of weeks? Did you want

him to look buff, is that a term similar to—synonymous with ripped? I am not an athlete.

Mr. CONKLIN. I guess ripped is more specific to showing muscle definition. Buff might be muscular.

Mr. WALDEN. All right. I am learning as we go here.

So you wanted him to get ripped so he would look good on camera. Was John Jay Murphy somebody who was going to use your product or testify on camera that he was a user of your product and had gotten results?

Mr. CONKLIN. Actually, he was a success story who had sent photographs to me after he achieved the success on Xenadrine. And we were contemplating the other training video, and he was one of the potential candidates to be used in that. And, of course, if he is going to be on a video, we would like him to look good.

Mr. WALDEN. Yes. Okay.

Mr. CONKLIN. Now this is sometime after he had originally gotten through the transformation process.

Mr. WALDEN. How long was he on your product?

Mr. CONKLIN. He was very short term, but I am not quite sure, sir.

Mr. WALDEN. How much weight did he lose? How much fat did he lose?

Mr. CONKLIN. Once I am not—I do not recall. There were so many that I do not specifically recall his weight or his fat loss.

Mr. WALDEN. I see. If you could supply that for the committee at some point, it would be helpful.

Mr. CONKLIN. Yes, sir.

Mr. WALDEN. We are trying to figure out, you know, how accurate the claims were here.

And so he is a real person, he gets ripped. You want him to look his best on camera. Obviously, to put the best face on your product?

Mr. CONKLIN. That is correct.

Mr. WALDEN. Or best abs or whatever it is he is putting on your product.

Mr. CONKLIN. Well, this is, like I said, sometime after he had sent his photographs to me. So I did not know what kind of shape that he was in.

Mr. WALDEN. All right. So you remember he sent the photos, but you do not recall but you will supply for us how much weight he lost that he attributes to your product?

Mr. CONKLIN. I do not remember, sir.

Mr. WALDEN. No, but you will supply it for us?

Mr. CONKLIN. Yes.

Mr. WALDEN. Did any physician like Dr. Colker ever evaluate these success stories to ascertain their veracity?

Dr. Colker, I mean, were you using success stories in advertising, did you take a look at them and say they meet some criteria?

Dr. COLKER. No, I did not.

Mr. WALDEN. Anybody in the company do that to verify that these were real success stories? Mr. Conklin?

Mr. CONKLIN. We got signed affidavits, sworn affidavits from the people.

Mr. WALDEN. Okay.

Mr. CONKLIN. Attesting to their weight loss.

Mr. WALDEN. All right. So nobody checked beyond that? They just told you. And how much did they get paid? What do you pay somebody to come in that looks ripped?

Mr. CONKLIN. Well, they do not get paid if they just send photographs in, it is if they are used in any advertising.

Mr. WALDEN. Yes. If they are used in a video that you do, what do you pay them generally?

Mr. CONKLIN. For an ad, I believe a couple thousand dollars.

Mr. WALDEN. Really?

Mr. CONKLIN. Yes.

Mr. WALDEN. So there is a real incentive. But so they just can sign an affidavit that says I swear I took whatever it is and look at me now, and you use them and nobody checks? There is no controlled study, is that right, no control on this?

Mr. CONKLIN. Well these—

Mr. WALDEN. They just tell you they took it? No doctor reviews it?

Mr. CONKLIN. Well, these were photographs that we received after he had made his transformation. So—

Mr. WALDEN. But in general. Have anybody in any of your videos, do you do any kind of quality control to make sure they are telling you the truth?

Mr. CONKLIN. We look into it.

Mr. WALDEN. Who looks into it?

Mr. CONKLIN. I would look into it. I would—they would send typically a letter with their photographs outlining their progress and then they would sign a sworn affidavit.

Mr. WALDEN. Do you do any kind of blood tests to make sure they are not on steroids rather than ephedra/cafeine products?

Mr. CONKLIN. No. We do not do blood tests.

Mr. WALDEN. How do you know then? I mean—

Mr. CONKLIN. Well, I believe—

Mr. WALDEN [continuing]. With any certainty?

Mr. CONKLIN. I believe in the agreement that they sign they are swearing that they have not used any other illicit drugs or any drugs otherwise.

Mr. WALDEN. But you do not do any blood tests to check?

Mr. CONKLIN. No, sir, we do not.

Mr. WALDEN. Huh. All right. All right. Well, interesting.

Is Mr. Murphy a friend of yours from the gym?

Mr. CONKLIN. No, he is not.

Mr. WALDEN. He is not? Huh. All right.

What is his profession?

Mr. CONKLIN. He is a medical doctor.

Mr. WALDEN. Mr. Murphy is a medical doctor?

Mr. CONKLIN. Yes, he is.

Mr. WALDEN. Okay. Does he do any kind of body building or is he a professional body builder as well?

Mr. CONKLIN. I do not believe he's a body builder, no.

Mr. WALDEN. Okay. Does he have an agent?

Mr. CONKLIN. I am not sure.

Mr. WALDEN. Maybe somebody named Michael Snell? Does that name ring a bell?

Mr. CONKLIN. Michael Snell may have been the person who sent his photographs originally to me, yes.

Mr. WALDEN. Would a person who send somebody else's photos usually be considered an agent?

Mr. CONKLIN. Not always. Sometimes they are a friend of theirs. Sometimes they call themselves an agent when, in fact, they are just a friend whose—

Mr. WALDEN. Do you enter into an agreement with Mr. Snell, has your company ever done that?

Mr. CONKLIN. I do not believe so, no. It was directly with John Murphy.

Mr. WALDEN. Okay. All right.

Did Cytodyne ever hire people to gain and then lose weight for the purposes of advertising? Mr. Chinery.

Mr. CHINERY. No, sir.

Mr. WALDEN. Okay. Did not Cytodyne's choice of models come into question in a recent California suit, Park v. Cytodyne?

Mr. CHINERY. In that case there was one witness who had changed his testimony, actually testified completely inconsistent with his sworn statements that he had provided to the company earlier. And in that testimony he said for the first time he told the company that he had gained weight prior to starting his after program.

Mr. WALDEN. Did your company have the raw data to show that in fact his affidavit was not right?

Mr. CHINERY. I am not sure what you mean by the raw data.

Mr. WALDEN. Did you have the actual data, his amount of fat loss?

Mr. CHINERY. That would be based upon the affidavit that he provided to the company, which was a sworn affidavit, sworn under penalty of perjury.

Mr. WALDEN. And what you are telling me if I understand it right is that he lied in that affidavit to your company? Is that what you are saying?

Mr. CHINERY. That is my belief, yes.

Mr. WALDEN. In fact, did not the judge in that case state, and I quote: "Since both Mr. Chinery and Mr. Conklin were aware of the inconsistent information, the claims in advertising regarding a hired model's fat loss and muscle mass gain are evidence of defendant's willingness to stretch the truth to make its product appear to be more effective than it actually was." That is a quote from the judge.

Mr. CHINERY. I believe that was his own opinion on that. But I strongly disagree with it.

Mr. WALDEN. How long was that trial?

Mr. CHINERY. I believe it was between 6 or 7 weeks.

Mr. WALDEN. Okay. Look at Tab 2. We have an email here where ABC Channel 7 New York contacted you about your product in April 2001. You referred the reporter to Dr. Colker so that she could hear from "an independent research scientist that is one of the foremost authorities in the world on ephedrine." But before you gave the reporter Dr. Colker's contact information you quote "went over with him" so that "he is clear that he is not to mention our company and is an independent researcher."

Do you make it a habit to not disclose all pertinent information to the press or the public when the spotlight is on your company?

Mr. CONKLIN. So is that directed to me? That would be on my email?

Mr. WALDEN. It is your email. Yes, I am sorry. Yes. Yes. To Bob C.

Mr. CONKLIN. Okay. In that case——

Mr. WALDEN. I want to make sure you have it. Tab 2. Okay.

Mr. CONKLIN. This is Dr. Colker who, as he has on several other occasions, spoken as an independent researcher not on behalf of the company.

Mr. WALDEN. Okay. But if I read this right, I thought you referred this to the reporter so that she could hear from an independent research scientist. Yet, did not Dr. Colker do work for your company? Was he not on a retainer?

Mr. CONKLIN. Yes, sir, he was, but he was not an employee. And——

Mr. WALDEN. Well, what's the difference between somebody on a retainer and somebody who is an employee? Is that—it seems to me that if I am on a retainer, I am not as independent as if I am not either an employee or on a retainer.

Mr. CONKLIN. Well, he has done consulting and he still may for other companies other than Cytodyne.

Mr. WALDEN. But he was on Cytodyne's cost of doing business, right? How much were you paying him, Mr. Chinery, do you know at that time, 2001?

Mr. CHINERY. I believe at that time it was in the range of around \$5,000 per month.

Mr. WALDEN. \$5,000 a month? On a retainer? And yet Mr. Conklin, I guess, tells the press here that he is independent. Do you believe him to have been independent?

Mr. GREENWOOD. This will have to be the gentleman's last question.

Mr. WALDEN. Oh, I am sorry.

Mr. CHINERY. In a certain capacity, yes. Because Dr. Colker has done a lot of research for a lot of other companies and other products, and we do consider him an expert on the subject of dietary supplements.

Mr. WALDEN. Mr. Chairman, could I just ask one question of Dr. Colker?

Mr. GREENWOOD. Quickly.

Mr. WALDEN. Do you consider yourself independent when you are paid \$5,000 a month by a company?

Dr. COLKER. I did.

Mr. GREENWOOD. It is all the independence money can buy.

The Chair recognizes himself quickly for two questions directed to Metabolife officials.

Metabolife officials have repeatedly said that they are interested in both consumers' health and in mandatory reporting of adverse events to FDA, yet the company did not voluntarily send to FDA copies of adverse event reports until August 2002. Why not?

Mr. HERMANN. Congressman, I do not know the reasons specifically of why those were not turned over until last year.

Mr. GREENWOOD. Okay. Do you know, Mr. Schreck?

Mr. SCHRECK. I have no idea why they were not turned over prior to 2002.

Mr. GREENWOOD. Okay. With that, would you please respond to this committee in writing on answer to that question, which is, and we will be happy to provide you with a copy of it, Metabolife officials have repeatedly said they are interested in both the consumers' health and in mandatory reporting of adverse events to the FDA, yet the company did not voluntarily send to FDA copies of adverse events reports until August 2002. And we would like to know why not.

Let me ask you one final question before we end the hearing. Dr. Steven Heymsfield has testified that he was involved in two studies of ephedra conducted by ST&T on behalf of Metabolife. After Dr. Heymsfield declined to provide a statement that would benefit Metabolife in a civil lawsuit the company had filed, Dr. Heymsfield said the company terrorized him, told him that "they were at war" according to an interview that the doctor had with the Department of Health and Human Services. He reported that the consequences of Metabolife's actions almost ended his career.

Dr. Heymsfield also told his interviewers at HHS that although he was never requested by Metabolife to alter his data, he was encouraged to adjust his interpretation of that data.

Mr. Schreck, you were not an employee of Metabolife at that time, were you?

Mr. SCHRECK. No, I was not.

Mr. GREENWOOD. Okay. Even so, how does Dr. Heymsfield's story reflect upon your company's tactics in trying to obtain scientific results to boost your claim that Metabolife 356 is safe?

Mr. SCHRECK. Well, without previously seeing a document that you are talking about—

Mr. GREENWOOD. Look at Tab 104, please.

Mr. SCHRECK. I'm sorry.

Mr. GREENWOOD. Turn to Tab 104.

Mr. SCHRECK. Thank you. Is there a specific section of 104 you would want us to look at?

Mr. GREENWOOD. Page 8.

Mr. SCHRECK. Page 8?

Mr. GREENWOOD. Yes.

Mr. SCHRECK. There is no page numbers on the bottom of this, so I will count them out.

Mr. GREENWOOD. Well, I will tell you what I am going to do, Mr. Schreck. You are the new CEO. You are telling us you do not know anything about this. What I would like to ask you to do is to go back to your company and you conduct an investigation within your company. And I would like you to find out whether in fact who was involved in these contacts with Dr. Heymsfield and whether or not he was encouraged to adjust his interpretation of that data and at your leisure take a look at that tab, review it and interview individuals at your company and provide this committee with a response as to what you found out. Would you do that for us, sir?

Mr. SCHRECK. Yes.

Mr. GREENWOOD. And would you also do that, you have also indicated in response to my previous question that you do not know

why it is that the company waited until August to send these adverse event reports to the FDA. I would like you to also find that out for us.

Mr. SCHRECK. Yes.

Mr. GREENWOOD. Do an investigation, ask your people and get back to us in writing. Would you do that, sir?

Mr. SCHRECK. Yes, Mr. Chairman.

Mr. GREENWOOD. Thank you.

It has been a long day, a very, very long day for all of you. I thank all of our witnesses for their patience and forbearance.

I thank our members for theirs as well.

And this hearing is adjourned.

[Whereupon, at 7 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

MICHAEL M. BADEN, M.D.
NEW YORK, NEW YORK 10019
17 July 2003

Honorable JAMES C. GREENWOOD
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515-6115

Re: Death of Steven Bechler

DEAR CHAIRMAN GREENWOOD: I have been retained by Arent Fox, attorneys for Cytodyne Technologies, to review and evaluate the death of Mr. Steven Bechler. I am the former Chief Medical Examiner of the City of New York, and I was the chief forensic pathologist for the United States House of Representatives Select Committee on Assassinations that investigated the deaths of President John F. Kennedy and of Dr. Martin Luther King Jr. from 1977 to 1979.

I have reviewed the autopsy report and Broward County Medical Examiner's Investigative Report; the toxicology reports of Broward County, National Medical Services and Aegis Analytical Laboratories; literature relied upon by Chief Medical Examiner Dr. Joshua Perper; transcripts and video of Dr. Perper's press conferences; the Rand Report on Ephedra and Ephedrine prepared for the U. S. Department of Health and Human Services of February, 2003; the Cytodyne Technologies responses to Congressman W.J. "Billy" Tauziri's requests for information about Xenadrine RFA1 dated March 14 and March 25, 2003; the Florida District Medical Examiners Office reports of past heat stroke deaths in their jurisdictions; and a February 19, 2003 ESPN article entitled "Family: Bechler had heatstroke while in high school" in which the decedent's mother is quoted as saying that her son had had two prior episodes of heat stroke while playing baseball in high school when he was 16 and 17 years old. The above were forwarded to me for review by Arent Fox. I have also spoken to Dr. Perper by telephone about this death.

I have not had access to the EMTFire Rescue records of February 16, the North Ridge Medical Center Hospital records of February 16 and 17, past medical records, the autopsy microscopic slides and photographs, and the interviews of the witnesses to Mr. Bechler's collapse and initial treatment.

Mr. Bechler was 23 years old and overweight when he arrived in Florida for spring training in February of 2003. His weight was listed as 249 pounds; in 1998 it had been 190 pounds. A routine physical examination after arriving at training camp showed his blood pressure to be extremely high, at 150/112. It later dropped to "150/92"; his pulse was very rapid at 96 beats per minute. He was known to have a history of untreated high blood pressure and of liver disease. His liver function tests were abnormal and it had been previously documented that he had a fatty liver, possibly caused by his obesity. His very high blood pressure readings alone upon arriving at the training camp as well as his increased weight and liver disease, in my opinion, should have caused delay of his exercise training until he was further evaluated medically.

On February 15, Mr. Bechler participated in the morning training exercise but was unable to complete the final run, didn't feel good and went home. On February 16, with the outdoor temperature at 85° Fahrenheit and the humidity at 75%, he again could not complete the final run, but this time, he fell to the ground, could not stand up, vomited and was noted by the Assistant Trainer to be hot. He was

taken to the training room, given oxygen by mask and cooled with ice packs behind his neck. He was unable to drink offered fluids. His temperature was found to be 106° and his blood pressure was 160/90, with rapid pulse and rapid breathing. Fire Rescue was called at 11:39 a.m. It is not clear from the records presently available to me how much time elapsed after Mr. Bechler's collapse on the field until Fire Rescue was called. When Rescue arrived, Mr. Bechler was "unresponsive," his pulse was extremely rapid at 210, incompatible with proper functioning of the heart; his blood pressure was listed as "160/p," which indicates shock; and his respirations were extremely rapid at 36 beats per minute. Intravenous fluids and Narcan were administered; Narcan is the specific antidote for a narcotic drug overdose such as from heroin, morphine or oxycodone. He did not respond. He vomited "large amounts" requiring suctioning en route to North Ridge Hospital, where he arrived at 12:23 p.m. His temperature was 108 degrees and a diagnosis was made of heat stroke. He remained comatose, developed severe multiple organ failure and was pronounced dead 23 hours after admission to the hospital.

The autopsy report confirmed that Mr. Bechler was markedly obese with a scale weight at the medical examiner's office of 320 pounds 71 pounds more than listed by the team trainer two days earlier. His height is mistakenly listed in the autopsy report as 62 inches. Assuming that his proper height is 6 feet 2 inches, as is indicated in press reports, Mr. Bechler's Body Mass Index (BMI) would be 41, establishing him as morbidly obese. The autopsy also showed that his abdominal fat pad the panniculus adiposus was 4 cm thick, consistent with his weight of 320 pounds, and confirmed that he had a fatty liver. His heart was enlarged to 450 grams. He had heart and kidney disease due to the harmful effects of untreated high blood pressure. Toxicologic testing showed the presence of ephedrine, a weightreducing drug, and twice the normal amount of DHEA, a naturally occurring steroid, also available as a dietary supplement because it is believed by some to enhance athletic performance and to help in losing weight. It is of interest that Dr. Perper states in his report that in 2001 one of Mr. Bechler's physicians had told him to avoid steroid supplements and alcohol consumption. Review of medical records is needed to determine why this warning was necessary.

The ephedrine level in Mr. Bechler's blood continued to rise for three hours after he collapsed and while he was in the hospital, which Dr. Perper stated in his March 13 report indicated that much of the ephedrine taken by Mr. Bechler "was still in an absorption stage" when he arrived at the hospital. This means that at the time that Mr. Bechler collapsed from heat stroke much of the ephedrine he had swallowed was still in his stomach and had not yet entered his bloodstream and, therefore could not have produced any harmful physiologic effects; the unabsorbed ephedrine and the ephedrine in Mr. Bechler's vomitus could not have caused or contributed to Mr. Bechler's death. Dr. Perper, however, had publicly committed himself at a press conference on February 18, the day of the autopsy, stating that Xenadrine had been found in Mr. Bechler's baseball locker, that it contains ephedrine and that the ephedrine significantly contributed to Mr. Bechler's death from heat stroke this conclusion was reached before toxicologic and microscopic studies were completed and before full medical information could be obtained.

Ephedra refers to a species of plants, which includes the Chinese herb ma huang, which contain ephedrine, a pharmacologically active drug used as a nasal decongestant, as a bronchodilator and to raise low blood pressure, and is similar to epinephrine (adrenaline), which is a normal body hormone. It is also used to lose weight. The terms ephedra and ephedrine are often used interchangeably.

At the March 13 press conference, Dr. Perper acknowledged that he knew of no prior instance in which ephedrine had caused a death from heat stroke. He also stated that no other drugs were found in Mr. Bechler's blood on admission to the hospital, despite the toxicologic finding of increased DHEA, which is not present in Xenadrine.

During that same press conference, Dr. Perper referred to the Rand Report. The Rand Report found no evidence not a single case in an extensive review of the literature and of reported adverse effects, that ephedrine had caused any heat stroke deaths. Similarly, Cytodyne, in its responses to Congressman Tauzin, Chairman of the House Committee on Energy and Commerce, documented that it had had no reports of Xenadrine RFA1 causing a death from heat stroke after more than 2 billion capsules had been sold. A MEDLINE search of the National Library of Medicine's database of scientific articles in 4,500 biomedical journals worldwide since the 1960's, showed not a single report linking ephedra or ephedrine to heat stroke. The Physician's Desk Reference (PDR) does not list heat stroke as an adverse effect of ephedrine.

Dr. Perper specifically referred to an editorial by neurosurgeon Dr. Julian Bailes, published in the Journal of Neurosurgery in 2002, as of particular importance in

his reaching the conclusion that ephedrine was a significant factor in causing Mr. Bechler's death. However, Dr. Bailes does not describe or refer to a single instance in which ephedrine caused a heat stroke death. He merely cites statistics in which heat stroke deaths among football nationwide were 4.4 per year between 1965 and 1974, 1.7 per year between 1975 and 1984, 0.6 per year between 1985 and 1994 and were back to 4 deaths per year between 1995 and 2000. Not one of these deaths was linked to ephedra. However, Dr. Baffles proposed that since there was an increase in the use of dietary supplements and of ephedrinelike compounds between 1995 and 2000, they might be the cause of the slight increase in heat stroke deaths. Correlation is not causation. This is pure speculation by Dr. Baffles and is not a basis upon which a medical examiner can make a cause of death determination.

A number of Letters to the Editor written in response to Dr. Baffles' editorial in that same Journal disagreed strongly with Dr. Baffles' opinion that ephedra causes or contributes to heat stroke. One, signed by 12 sports medicine specialists, exercise physiologists, neuroscientists, and researchers from around this country and England cited 66 references and concluded that obesity was the most important risk factor in causing heat stroke: "According to the National Center for Catastrophic Sport Injury Research statistics, most heatrelated deaths in recent years have occurred in individuals who weigh more than 250 pounds, with many athletes weighing more than 300 pounds." The authors also stated that there was no evidence that ephedra increased the risk of heat intolerance or of heat stroke.

Dr. Bailes, in responding to these critical letters, conceded that many factors could contribute to heat stroke. "These multiple other factors," he wrote, "include the relative dehydration of the athlete before participation, heat acclimatization, the amount of heat and humidity exposure, the intensity of exercise, the design of the athlete's clothing and/or uniform, fluid replacement, the athlete's underlying medical or cardiac structure, the simultaneous ingestions of substances or medications that may interact, excessive dosages, genetic disposition, medical management and other possible variables." At the time of his collapse, Mr. Bechler had not yet had the ability to acclimatize to the Florida weather; he was suddenly attempting to exercise intensively; he had severely impaired underlying medical and cardiac "structure" with known liver and heart disease and high blood pressure, and had had an extremely high blood pressure reading of 150/112, without further evaluation and treatment, just before engaging in intense exercise; there may have been a delay in appropriate medical management; and there is a history that Mr. Bechler had experienced prior heat strokes.

Mr. Bechler's obesity is of particular concern. Dr. Perper assured me that the medical examiner's body scale is accurate and that Mr. Bechler weighed 320 pounds when he was brought there. Mr. Bechler was much more overweight, with attendant increased health risks, than the trainers realized. The 70 pound weight discrepancy cannot be explained by excess hospital fluid administration in the 23 hours he lay in the hospital; it would require delivery of more than three pounds of fluid per hour without any hospital personnel realizing that there was something wrong, while continuously adding intravenous bags. Further, the autopsy showed no evidence of such extreme overhydration in the body tissues or in the body cavities.

I agree with Dr. Perper that the cause of Mr. Bechler's death was heat stroke. However, I disagree as to the cause of this heat stroke. Mr. Bechler's poor health, vigorous exercise in hot, muggy weather, severe obesity, abnormal fatty liver, untreated high blood pressure, and enlarged heart are competent factors in and of themselves to be causes of heat stroke. The coincidental toxicologic finding of ephedrine, which is not known to produce heat stroke, in my opinion should not have been linked to the death by the medical examiner just as the medical examiner did not link the finding of the increased level of DHEA to his death.

It is my opinion, to a reasonable degree of medical certainty, based on all of the materials I have thus far reviewed, on my training and on my 43 years experience as a medical examiner, that Mr. Bechler died of a heat stroke precipitated by his morbid obesity, high blood pressure and heart disease, adverse weather conditions, physical exertion, and inadequate screening, monitoring and medical supervision; that Xenadrine did not cause or contribute to Mr. Bechler's death; and that proper and prompt treatment with intravenous fluids and cold wraps immediately after he collapsed but was still conscious may have prevented Mr. Bechler's death.

My opinions are subject to modification when more information, including Fire Rescue and medical records, become available.

Yours very truly,

MICHAEL M. BADEN, M.D.

Sworn to before me this 18th day of July, 2003

JANET AMERASINGHE, LICENSE NO. 01AM4789617, QUALIFIED IN NEW YORK COUNTY COMMISSION EXPIRES 6/30/2007

METABOLIFE RESPONSE TO COMMITTEE QUESTIONS

As requested by members of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations in its hearing on ephedra on July 23, 2003, Metabolife International, Inc., submits the following supplemental written statement.

Metabolife believes that labeling is the key to informed consumer choices. Appropriate labels can adequately inform consumers about ephedra products and their use. There are benefits and risks that accompany the use of all products. Consumers can make informed choices about whether a product is right for them when they have access to complete, accurate, and science-based information about how to use the product safely as well as information on the product's benefits and risks. For these reasons, Metabolife supports the FDA's proposed labeling requirement for supplements containing ephedra.

Metabolife's label has evolved over time, in part due to changing state law requirements. In November 1999, the Metabolife 356 label was changed to include the language "Exceeding recommended serving may cause serious adverse health effects including heart attack and stroke." This label change was made to comply with the requirements of the Texas Ephedra Rule, effective November 1, 1999. (Texas Administrative Code, Title 25, Part 1, Chapter 229, Subchapter Y, Rule §229.462(2)). Metabolife generally supported the regulatory and legislative efforts in Texas, including a ban on the sale of ephedra products to minors, even though, based on the best available science, Metabolife does not believe that a causal connection has been established between the use of its products taken as directed and certain outcomes required to be placed on its label.

Metabolife established its consumer information line as a means for its customers to ask general questions about the proper use of its products and assist them with their weight loss questions. Between 1997 and 2002, only about 3 of every 100 calls pertained to health related issues. Moreover, based on the GAO's count, only about 6 out of every 1000 of these health related calls pertained to significant health allegations, such as stroke or heart attack. It is Metabolife's policy to tell customers who report a negative experience with the product to discontinue product use and consult a physician.

Employees who staff the consumer information line have been advised that Metabolife is a dietary supplement company and not a drug company, and that terms like "side effect" are not applicable to Metabolife 356 because they imply that it is a drug. This is supported by Stedman's Medical Dictionary, 26th Edition, where the definition of "side effect" is: "A result of drug or other therapy in addition to or in extension of the desired therapeutic effect; usually but not necessarily, connoting an undesirable effect. Although technically the therapeutic effect carried beyond the desired limit (e.g., a hemorrhage from an anticoagulant) is a s.e., the term more often refers to pharmacologic results of therapy unrelated to the usual objective (e.g., a development of signs of Cushing's syndrome with steroid therapy)."

Metabolife supports mandatory reporting to the FDA of serious or significant anecdotal health-related consumer complaints based on criteria and definitions to be established by the FDA and industry that are consistent and understandable, together with an objective standard and appropriate method of evaluation by industry and the FDA. To this end, in early 2002, Metabolife, through its regulatory counsel, retained Life Sciences Research Office ("LSRO"), a private, non-profit organization, to undertake a review of non-adverse event reporting systems, such as Metabolife's call line, as well as existing adverse event reporting models, and make recommendations regarding an adverse event collection and reporting system appropriate for dietary supplement products. LSRO was established in 1962 by the Federation of American Societies for Experimental Biology and is known and respected for studying fundamental problems in biomedicine, healthcare, nutrition, food safety, and the environment, including for various government agencies. LSRO's reports are independent in nature and developed in a transparent process. Although the LSRO report will not necessarily reflect the views of Metabolife on the issue, we believe that the report, which is expected to be available in the Fall of 2003, will be an important contribution to the development of a responsible, reliable industry-wide reporting system.

Metabolife has provided the FDA with unredacted call records based upon assurances under federal law that personal information will not be made public. It is this concern for the privacy interests of its customers that has guided the Company in dealing with requests for production of its call records.

Metabolife has taken proactive steps to ensure that Metabolife 356 actually contains what the label says it contains. Despite the fact that the FDA has yet to issue a final rule establishing Good Manufacturing Practices ("GMPs") for dietary supple-

ments, Metabolife has implemented quality control procedures, such as voluntary batch-testing of each lot of ephedra-containing product, that meet or exceed GMPs for food. Metabolife urges the FDA to require such stringent GMPs for all manufacturers of dietary supplements. Metabolife discontinued the inclusion of bovine complex as an ingredient in Metabolife in approximately July 2002. Bovine complex consists of a combination of ovary, orchic, uterus and prostate glands of a cow. This ingredient was included in the formula because it provides beneficial amino acids. Metabolife removed bovine complex from the Metabolife 356 formula because of publicity surrounding issues with Mad Cow Disease in other countries. While Metabolife continues to believe the bovine complex is a safe and healthy addition to the formula, it was removed because it was not an essential ingredient in the formula and removing the ingredient would not alter the effectiveness of the product.

Among other ingredients, Metabolife 356 contains royal jelly, a thick, milky-white, creamy liquid secreted by the hypopharyngeal glands of nurse bees. Commonly found in dietary supplements, royal jelly is a very rich source of proteins and contains eight essential amino acids, carbohydrates, and beneficial lipids, including the important fatty acids sterols and phosphorous compounds as well as acetylcholine.

During the hearing a question arose regarding Metabolife's interaction with Dr. Heymsfield. As reflected in the FDA interview cited below, the Company did not seek to have Dr. Heymsfield alter or adjust scientific data concerning Metabolife 356. Dr. Heymsfield was involved in two studies concerning ephedra dietary supplements: an eight-week study and a six-month study. With regard to the eight week study, Dr. Heymsfield told FDA investigators "No requests were made to change data or comments regarding adverse events." See FDA Memorandum of Interview, Oct. 18, 2001, p. 3.

With regard to the six month study, Dr. Heymsfield "re-iterated a number of times that he was never requested by Metabolife to alter or adjust data..." *Id.* at 8. The FDA Interview Memorandum contains a vague allegation that "he was encouraged (pushed) to adjust his interpretation of the data," but does not explain what is meant by this. Other portions of the Interview Memorandum indicate that he did not have access to the relevant data to provide any interpretation of it. According to the FDA Interview Memorandum, "he did not see any patients, he did not review any charts, the study results were not shared or discussed with him and he was not a co-author of any abstract or presentation of study results." See *id.* at 4. Also, according to the Interview Memorandum, Dr. Heymsfield indicated that he "was not informed of any adverse events that occurred during the second study, and raw or summary data were not shared with or evaluated by him." *Id.* at 5. The six-month study was supervised by the principal investigator, Dr. Carol Boozer. The Interview Memorandum reflects that Dr. Heymsfield stated that "Dr. Boozer does have a lot of scientific integrity." See *id.* at 8.

According to a *Washington Post* story, Dr. Heymsfield said that "he wouldn't hesitate to recommend a patient trying Metabolife as long as he knew the patient didn't suffer from high blood pressure, heart disease, or other maladies mentioned in the warning label." See Charles Babcock, "Stimulant Propels Diet Empire," *Washington Post*, May 24, 1999, Section A.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The American College of Obstetricians and Gynecologists and its 46,000 partners in women's health care, thanks Chairman Greenwood, Ranking Member Deutsch, and the entire Committee for holding this important hearing concerning ephedra and its use in dietary supplements. As physicians dedicated to improving women's healthcare, we are particularly concerned with the effects ephedra has on the life and reproductive health of women. We believe that there are many unknown risks for women, especially pregnant women, who may use these supplements, and believe it is appropriate for Congress to seriously consider measures to ensure the safety of products that can be bought so easily over the counter.

Increasingly, evidence points to the serious adverse effects associated with ephedra use. It has been reported that individuals using these products have suffered heart attacks, strokes, seizures and even death. Even more troubling to ACOG Fellows, is the potential for damage to pregnant women using ephedra and the effects its use may have on a fetus. The FDA has already stated that pregnant women should avoid the use of dietary supplements with ephedrine alkaloids, and the effects of these substances on fetuses are undetermined.

Women often take ephedra for weight loss although current evidence does not support its effectiveness. Thus, they are exposing themselves and, should they become pregnant, their fetus, to unknown effects. It is estimated that almost 50 percent of pregnancies are unplanned, so even if warnings are given, many women will have already used ephedra before they know they are pregnant.

As members of the Coalition for Anabolic Steroid Precursor and Ephedra Regulation (CASPR), we support efforts to regulate products containing steroid precursors and products containing ephedra. Members of CASPR include physician groups, the US Olympic Committee, as well as national sport organizations. We also strongly support legislation introduced by Representatives John Sweeney (R-NY) and Tom Osborne (R-NE), HR 207, the Anabolic Steroid Precursor Control and Health Education Act, that would allow the Attorney General to place these substances on Schedule III of the Controlled Substances Act, where they would be subject to the same strict safety requirements and controls as other controlled substances.

ACOG is encouraged by recent efforts undertaken by the Food and Drug Administration (FDA) to reduce the risks associated with the use of ephedra, and believe they represent a good first step. FDA has called for public comment on whether current evidence regarding ephedra use present a significant or unreasonable risk of illness or injury, and in late February of 2003, with limited authority, issued warnings to 26 manufacturers of ephedra-containing products, asking them to remove unproven claims about these controlled substances. ACOG urges additional Congressional action, including the adoption of HR 207, and, continued study of the side effects of ephedra.

ACOG thanks the Chairman and Committee Members for their leadership to examine current regulations regarding dietary supplements that contain ephedra and to examine the effectiveness and safety of these products. There are many unanswered questions with regard to extended use of ephedra, especially on certain populations, like pregnant women. We strongly believe that ephedra warrants additional regulation; the health and lives of hundreds of American women are dependent upon it. We look forward to working with Committee staff as they move forward on possible legislation or regulatory recommendations.

ISSUES RELATING TO EPHEDRA-CONTAINING DIETARY SUPPLEMENTS

THURSDAY, JULY 24, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION, JOINT WITH THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittees met, pursuant to notice, at 9:40 a.m., in room 2123, Rayburn House Office Building, Hon. Cliff Stearns (Chairman, Subcommittee on Commerce, Trade, and Consumer Protection) and Hon. James C. Greenwood, (Chairman, Subcommittee on Oversight and Investigations) presiding.

Members present, Subcommittee on Commerce, Trade, and Consumer Protection: Representatives Stearns, Shimkus, Shadegg, Bass, Terry, Tauzin (*Ex Officio*), Markey, Davis, Stupak, Green, McCarthy, and DeGette.

Members present, Subcommittee on Oversight and Investigations: Representatives Greenwood, Stearns, Shimkus, Bass, Walden, Terry, Tauzin (*ex officio*), DeGette, Schakowsky, and Waxman.

Also present: Representative Pallone.

Staff present: Dan Brouillette, staff director; Brian McCullough, professional staff; Alan Slobodin, majority counsel; Mark Paoletta, majority counsel; Kelli Andrews, majority counsel; Casey Hemard, majority counsel; Will Carty, legislative clerk; David Nelson, minority counsel; and Jessica McNiece, research assistant.

Mr. STEARNS. The subcommittees will come to order. Good morning everybody. Welcome to the joint hearing on Issues Relating to Ephedra-containing Dietary Supplements. I am Cliff Stearns, the chairman of the Commerce, Trade, and Consumer Protection Subcommittee; and the joint hearing is with Jim Greenwood, who is the chairman of the Oversight and Investigations Subcommittee.

Yesterday's hearing focused on dietary supplements that contain Ephedra, and the manufacturing and distribution of these products, while today we will examine their regulation and also the policies pertaining to these products in major league sports.

I appreciate my co-chairman's leadership in holding hearings about products governed by the laws under the jurisdiction of the committee. We want to promote healthy lifestyles, and ensure that Americans have good information and can promote their own wellness.

At the same time, we do not want products on the market that pose a significant safety risk based on scientific information.

Whether we like it or not, public figures are often, very often, role models for our society.

While we in Congress might like to think that we provide a positive role model for many younger Americans, any parents know that we have a very difficult time competing with high profile entertainment and sports celebrities that captivate youths.

Unfortunately for many celebrities, the proliferation of media coverage devoted to many of these stars have made their lives an open book. Details of their every move are chronicled on the nightly news, or in the morning paper, and their personal lives become directly linked to their professional lives.

An unwelcome loss of privacy may not be by choice and it has my sympathy, but a position of visibility nevertheless brings certain rewards. The benefit of having the podium, the bully pulpit, or the daily press coverage afforded provides an incalculable influence that translates into endorsements and drives entire industries.

And we have to look no further than the billion dollar sneaker industry for proof that today's sports idols influence American culture enormously. Yet the danger in emulation is always determining where to draw the line. Copying fashion trends set by celebrities may be harmless, but following their lifestyles could be inappropriate and unwise.

And that is why we are here today with a distinguished panel of witnesses representing American sports at the professional and collegiate level. The discussion and debate surrounding Ephedra has become largely focused on its safety because of the unfortunate recent deaths of a professional athlete, and a high school athlete, that have been linked to the use of the Ephedra products.

I believe that it is productive to examine the factors and information available that have led to the sports organizations to the decisions and actions taken by each regarding Ephedra. Sports organizations have taken it upon themselves to ban certain substances from their competitors, even when they are perfectly legal for the American public.

The policies are usually determined by two factors. First, substances are banned for either real or perceived performance enhancing qualities that could be detrimental to fair competition, and second, because they may pose health and safety concerns in some consumers.

I might remark that we learned at yesterday's hearing that the two Ephedra manufacturers who were witnesses, while they did not conjecture the reasons behind the league's decision, both testified that they support the ban, as that is not the audience to whom they are marketing their products.

It is important to keep these points in mind; the real or perceived performance enhancing qualities that would undermine the idea of a level playing field, and the health and safety concerns as Congress reexamines the manner in which supplements are regulated and marketed today.

And I am pleased that we have the Federal Trade Commission and the Food and Drug Administration testifying on these subjects. Regarding the FDA, the Dietary Supplement Health and Education

Act of 1994, also known as DSHEA, passed the Congress with no dissenting votes.

It created a reasonable balance. Dietary supplement products may make a claim about general use, but not make unsubstantiated claims, nor can they market dietary supplements with unapproved disease claims. The labeling I have read on products containing Ephedra clearly affirms "that FDA has not evaluated" their statements, nor are "the products intended to diagnose, treat, cure, or prevent any disease." The American public should and does have access to safe supplements with accurate information. The law regulating dietary supplements provide FDA with the authority and framework to balance consumer access to and choice with the need to ensure the marketing of safe products and accurate information.

Unfortunately, the FDA has not fully implemented DSHEA. An important step that the FDA can take to ensure safe and quality products enter the marketplace would be to issue the good manufacturing practice guidelines that were a part of DSHEA.

These guidelines will establish basic standards so that the FDA inspectors can ensure supplements are being manufactured in a sanitary and pure fashion with appropriate labeling. I support the FDA's enforcing existing law rather than trying to create duplicative or expansive law, or ban Ephedra products without FDA meeting its burden of proving that it presents "a significant or unreasonable risk of illness or injury."

The consequences of any overreaching actions would be detrimental to American consumers by unjustifiably limiting access to information and products intended to help consumers make wise and educated choices. With that, I conclude my opening statement and I welcome the ranking member, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I thank you and Chairman Greenwood for holding this second day of hearings to focus on the harmful effects of Ephedra in dietary supplements. After hearing the tragic personal stories yesterday and examining the overall impact supplements that contain Ephedra have had on the American public, it has become very clear to me that this public safety issue merits congressional action.

Today our first panel consists of representatives from various professional sports organizations and the NCAA. While my primary concern is the safety of every day consumers and young people, I am also concerned about the effects of Ephedra on professional athletes.

I have some reservations about our subcommittee asserting itself into the internal discussions between professional sports players and management. While I believe that we should not interfere in collective bargaining issues, we do nonetheless need to look at the safety of substances like Ephedra.

The hearing yesterday clearly demonstrated to us that sports and Ephedra don't mix. Accordingly, the FDA has proposed a ban on any claim that Ephedra enhances athletic performance. However, while I believe that the FDA should regulate Ephedra in all forms, I do not believe that Congress should be legislating an Ephedra ban just for professional athletes.

I think that it should be banned overall until it is regulated. Our second panel consists of the Commissioner of the Food and Drug

Administration, and the Director of the Federal Trade Commission. I thank them both for being here to engage in this discussion about where we go from here.

Clearly, we need to do more to regulate harmful dietary supplements. We have a responsibility to keep them out of the hands of potential victims. I think that most reasonable people believe when they go into a store and shop for a product, such as a dietary supplement, that if they were not safe that they would not be allowed on the shelves of our convenience and grocery stores.

I think they are convinced that dietary supplements would not be available or sold if the Food and Drug Administration had not approved or somebody had not approved them for human consumption. Little do they know that they are actually pawns in a game of Russian Roulette.

With every bottle of supplements that they buy and each pill that they take, they are risking their health and even their lives. There is currently no guarantee that ingredient concentrations, including concentrations of Ephedra, are consistent in safe levels. Yesterday, we heard heartbreaking stories from the Bechler and Riggins families. Both sets of parents lost their sons as a result of taking Ephedra pills. These families represent the countless numbers of people who have been adversely affected by dietary supplements.

Every day young boys are drawn to the supplements in the hope of enhancing their athletic ability and our young women are seduced into believing that they will lose weight by simply popping pills.

I want to know how many more sons and daughters will have to die before these products are removed from the market. It is painfully obvious that the FDA has more than enough evidence to meet the burden of proof necessary to prevent these products from being so accessible to our children.

The government must show that there is "significant or unreasonable risk of illness or injury" in order to take regulatory action. Well, we have scientific evidence and we have anecdotal evidence.

We have a number of credible organizations, including the American Medical Association, and the American Heart Association, that oppose the sale of Ephedrine supplements because of the risks associated with these products. This committee needs to know today why the FDA has not taken more forceful action.

It is also critical that we keep in mind that this discussion does not begin and end with Ephedra. We are looking for a long-term solution, not a band-aid approach. As Members of Congress, we can prevent other Ephedra-like episodes through thoughtful policies.

We already know a dietary supplement called bitter orange is gaining in popularity. Very little is known about this new ingredient in Ephedra-free dietary supplements. Yet, it could lead to a similar fate.

Ephedra should be viewed as the canary in the coal mine that it is, and without regulatory changes, there could be no end to the life-threatening supplements that follow in Ephedra's wake. Current regulations that cover dietary supplements are loose at best, and completely ineffective at worst.

I know that the supplement industry argues otherwise. If that is the case, then why is there still such strong opposition to FDA regulation. Yesterday in his final words, Mr. Bechler asked us to make sure that his son and Sean Riggins did not die in vain. Let us commit ourselves to doing all that is necessary to grant his request. I thank you, Mr. Chairman.

Mr. STEARNS. I thank the gentlelady. The distinguished chairman of the full committee.

Chairman TAUZIN. I thank the gentleman. I think that perhaps you ought to recognize the chairman of the Oversight and Investigations Subcommittee.

Mr. STEARNS. The chairman of the Oversight and Investigations Subcommittee, Mr. Greenwood.

Mr. GREENWOOD. I thank the chairman for yielding, and good morning. I would like to thank my colleague, Chairman Stearns, for co-chairing the second day of the committee's examination of issues relating to Ephedra.

Yesterday, the Subcommittee on Oversight and Investigations heard some very disturbing testimony from grieving families, scientific and public health experts, and companies that manufacture Ephedra-containing products.

First, we learned that Ephedra represents a compelling health concern. Ephedra is disproportionately represented in the adverse event reports for supplements, and most Ephedra supplements involve ephedrine-caffeine combinations not permitted in prescription and over-the-counter drugs.

We learned that many of these supplements using this combination also add other ingredients, including in some cases even more stimulants. The interactions of these ingredients with the ephedrine-caffeine combination has never been studied.

The General Accounting Office testified that 44 percent of the adverse events reported to Metabolife between 1997 and 2002 involved younger consumers. The GAO also noted that the available information in the adverse events showed that most people were using the supplements at the recommended dosage and duration.

We learned about companies engaging in questionable conduct, such as manipulating research results to make the data more marketable. We heard how one company failed to release information to the FDA on nearly 15,000 reports of adverse events that they had received until they were under criminal investigation.

Company executives, when asked, could not explain what some of the ingredients were on the labels of the products that they sold. Another company continued to market its supplement products with street drug names for 3 years after a State Department of Health raised concerns on this very issue.

The lead researcher of a study touted by the Ephedra industry as the gold standard in support of the products admitted that the study could not be used to claim safety, and that it does not support the efficacy of any Ephedra product actually marketed in the U.S.

And under my questioning, this lead researcher, this expert on obesity, said that she admitted that she would not even recommend Ephedra supplements. She would not recommend them herself.

Ephedra has been linked to serious side effects, including stroke, seizure, heart attack, and death. At our hearing yesterday, I asked one of our expert witnesses, a cardiologist, who is also a professor of pharmacology and toxicology, whether an otherwise healthy person could die from simply taking an Ephedra supplement and his response was yes.

When children can buy Ephedra products in a convenience store, where it sits between the candy and the magazines, this seems to be an unacceptable risk. When companies appear to choose sales over safety, it is our responsibility to ensure that something is done about this.

I look forward to working with my colleagues to find a solution to this alarming situation. I would like to thank the witnesses for attending this morning, and before I yield back, I happen to be looking at Men's Health Magazine, which I subscribe to because some day I hope to look like that guy. No chance.

But if you go through this magazine from the beginning to the end, there are lots of articles about how you get to look healthy and be healthy. It is all about dietary restraint and discipline, and it is all about hard, hard workouts in the gym, working very, very hard to be healthy.

But right at the end, in the last couple of pages, there is an ad for xenadrine, and that let's us know that losing weight just got a whole lot easier and faster, too. It gives young people and old people like myself who read this magazine, the theory and the belief that you don't have to do what the expert on obesity told us yesterday if you want to be healthy. It is all about diet and exercise.

All you have to do is pop a pill, and then you look like these folks, and the interesting thing that we learned yesterday at the hearing was that when they used the models for these ads, all the model has to say is I used to look like that, and now I look like this, and it is because of your magic pills, and there is never even any evidence that the models ever took the pills.

So I think it is a complete charade. I think it is a disservice to our young people to think that the answer to their health quest lies in the magic pill of questionable value, and of questionable content, and of serious risk. I yield back the balance of my time.

Mr. STEARNS. I thank the gentleman. The gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I would like to thank both you and Mr. Greenwood, and our ranking members, for holding not only this hearing, but the number of hearings on dietary supplements that contain Ephedra.

This is the first time that our Commerce, Trade, and Consumer Protection Subcommittee has the opportunity to discuss dietary supplements containing Ephedra. Our colleagues on the Oversight and Investigation Subcommittee have been doing a wonderful job of investigating the issue.

And in these investigation hearings, the results are sure to go a long way in painting an accurate picture of the safety and effectiveness of supplements containing Ephedra. This issue comes under the Commerce, Trade, and Consumer Protection Subcommittee's jurisdiction because the Federal Trade Commission regulates the advertising of food, cosmetics, and dietary supplements.

Anyone who owns a television set is sure to have seen the commercials for pills that promise to safely and effectively shrink your waistline. No dieting, no exercise. Rationally thinking, we all know that it can't be that simple. Yet, as most Americans struggle with their weight and they see more and more of these "before and after" photos showing slimmed down men and women, even rational people can think, "Maybe it is worth a try."

The problem, however, is that evidence is mounting that suggests that using Ephedra-based supplements as a weight loss tool or for enhanced athletic performance is neither safe nor effective.

The American Heart Association and the American Medical Association have called for the ban on Ephedra sales. Additionally, the Department of Health and Human Services has cautioned the public about the use of these supplements.

I am confident that the committee's investigation will yield informative results that will help guide Congress and Federal agencies in their determinations of what is the most appropriate action to take to ensure that the American public is informed about these supplements.

I also want to make sure that Congress is giving the FDA and the FTC the tools they need to meet their missions regarding these supplements. I am pleased to see in today's panel representatives from all our sports leagues, who have agreed to testify on their policies on Ephedra-based dietary supplements.

As a fan of the Houston Astros, the Houston Texans, the Houston Rockets, and University of Houston's sports programs, it is great to see the participation by both our professional and our amateur athletic associations. Both professional and amateur leagues must contend with another very important issue, which is the way that their policies and their actions affect their athletes, who are also our children.

American youth revere successful athletes, and often strive to achieve the same success. And while this certainly helps ticket sales, it also places a huge responsibility on the shoulders of both of our professional leagues and our athletes.

I am pleased to see that several leagues are sending strong messages to our children that Ephedra should not be taken to enhance athletic performance, and I look forward to hearing their testimony, Mr. Chairman, and I yield back.

Mr. STEARNS. I thank the gentleman. The distinguished chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman. Let me first thank the Subcommittee on Oversight and Investigation for an extraordinary hearing yesterday, and for doing such a good job again in calling the Nation's attention to problems in our society that in this case could mean life or death to some of our young people and those who are striving to become young athletes.

It was a pretty sad day to hear the story of a set of parents who lost a child because we made a decision here in Washington to exempt Ephedra from FDA regulation in 1994, when perhaps that decision made sense, and now we realize that perhaps it did not.

Yesterday's hearing was also a reminder that I hope will be carried through today's hearing, Mr. Chairman, and Mr. Chairman, you said something in your opening statement about the role mod-

els that today's superstars and athletes have become to young people.

I don't have to tell you that you can go into any young person's room and you will see a lot more posters of superstar athletes than you will see of any other politician in this town, and that is not going to change.

And Winston Churchill said that the price of greatness is responsibility, and I know that Vince Lombardi said that winning was not everything. Winning was the only thing. But when it comes to things like Ephedra and the use of products like Ephedra, and the fact that athletes have become such an enormous part of our lives, and star athletes have become such role models and such idols to so many young people, the message that is sent when enhancers and products like Ephedra are abused and used as a method of conveying to young people that you can look better, and you can be stronger, and you can be a better athlete if you only use these kinds of products, is I think a terribly wrong and irresponsible message.

I saw Sea Biscuit the other night, a story about a broken horse, and a jockey that was too big, a horse that was too small, and the lives that were twisted and broken, and all repaired because of this incredible horse, who as the trainer said during the movie didn't have it in his legs. He had it in his heart to win and become a great horse and a great winner.

And it occurred to me that when we think about the greatest of our sports heroes, we think of those like Sea Biscuit, whether it is a horse or a human being, who excel in sports. We think about the ones who didn't need any artificial help, and who just worked out with the gifts that they had and built themselves into something that we all looked up to and admired, and indeed our children wanted to emulate.

Ephedra is a good example of why we are going to have a debate on the House floor today about the necessity of the government protecting the safety of products, particular drugs, in our society, that can be used and abused in ways that I think the committee yesterday pointed out was happening in our society with Ephedra.

We made a decision to take the FDA mostly out of the game when it came to dietary supplements. Yes, the FDA does have a right to go in when safety concerns are raised, but by taking the FDA out and leaving it up to the industry to be responsible, we found out that perhaps we made a terrible mistake.

Now the sports industry is not responsible for regulating or enforcing responsibility when it comes to dietary products. But the fact is that today when athletes get sick, they often in the sports leagues have to ask permission just to take cold medicine that is sold over-the-counter.

And that is a burden in professional sports and athletics that may not seem fair, but it simply is a fact. So the question is that if athletes even have to get permission to get a cold medicine, why would any of the sports leagues permit the use of Ephedra.

We sent letters to all the sports leagues to determine what their policies were, and the answers that we got run the gamut. They run the gamut from one end to the other, and the reasons that we get are as varied as you could possibly imagine. The one consistent

answer that we got, and you are to be complimented for that, is that all the players are being strongly advised against using any supplement without consulting a physician. That is a good start.

That is a very good start. So I look forward to this meeting, Mr. Chairman, and ranking members, because it will give our committee a chance to explore further why there is such a wide gamut of answers when it comes to the use of a product like Ephedra, and the enormously important sports associations of our country.

We will also have a chance to finally hear from the FDA and the FTC, and we will finally be able to ask them why it took so long when we understand that athletes were using Ephedra going back to 1997, and why did it take so long for the FDA to get involved in the question of safety here.

And what the FTC can do about these advertisements, Mr. Chairman, that seem to improperly call upon young people to forget about the gym, and forget about how big your heart is, and how big your will is, and simply to supplement your way into potential greatness.

I don't think that there is a member on this committee that doesn't love sports. We all do. Our own Speaker, who was a wrestler and a wrestling coach, and he speaks often in sports lingo about the role we perform as public officials, and the need to be a good team, and to play fair, and to deserve to win, and to win the right way, and to win not just the issue, but to win the audience as we go about our business.

And we are anxious as all Americans to know that the young people who aspire to greatness in athletics in our country do so following the right role models, and they don't get trapped into something that hurts them, and damages them, and as we learned yesterday could kill them.

And we have got some work to do to repair that damage, and I think that today's hearing will teach us a lot, and today's vote on the floor, I want to remind all members, is another chance for you to say that you believe that the government has the responsibility to protect Americans from unsafe products and drugs.

And that whether they are manufactured in this country because we allowed them to be manufactured and sold without proper oversight, or whether they sneak across the border in packages that contain diluted and counterfeit, and rotten products that are being sold to Americans because they are desperate to get cheaper products, we have a responsibility to protect Americans from that kind of a regime.

And to protect young athletes from the kind of products that we are learning about in these hearings today that could end up harming them and in some cases unfortunately even taking their lives. Thank you, Mr. Chairman.

Mr. STEARNS. I thank the chairman. The gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. If I waive my opening, do I get extra time for questions?

Mr. STEARNS. That's true.

Mr. STUPAK. Then I will waive.

Mr. STEARNS. All right. And then you will get 8 minutes.

Mr. STUPAK. Thanks.

Mr. STEARNS. Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman. I will put my full statement in the record and simply make some remarks here at the outset. I want to compliment you for holding this hearing. I think it is important and I want to compliment you and the chairman of the Oversight and Investigations Subcommittee for your work, both yesterday and today.

And I think that this is an incredibly important topic and I share the concerns of the committee chairman and the others working on it. I am one who generally believes that it is the job of individuals to protect themselves, and to be essentially caveat emptor, for the buyer to beware.

But I think that Ephedra is a great example of those instances where, particularly for some people in our society who are not yet mature enough, the government indeed has a proper role.

In this instance, and I would like to associate myself with the remarks that have already been made by a number of our colleagues, I think that America's young people are being sent the message—and as the magazine that my colleague, Mr. Greenwood held up—that on the one hand we are urging you to eat all these bad things. On the other hand, we are telling you that the appropriate way to deal with that is to eat the right food and to get exercise.

Then we hold out this pill, and the pill is the magic way to lose weight. You won't really have to work at it, and you don't really have to discipline yourself in your eating habits, and you really don't have to exercise yourself in your exercise habits. Just take this pill.

Having struggled with my own weight all my life, and watching young people in this circumstance, I think it is a grave issue when we hold out essentially a promise of something for nothing. Take this pill and you can go ahead and eat whatever you want, and stay on the couch, and you will solve your own problems.

Now that simply is not the case. When the pill is dangerous, as I believe some of the evidence here suggests and as the testimony yesterday suggested, there can be dire consequences.

So I compliment you again for holding this hearing. I look forward to hearing as much of the testimony of the witnesses that I can. Unfortunately, as I had yesterday, I have a mark-up across the hall that is somewhat contentious, and where there will be a number of recorded votes, and I may have to miss a part of the hearing. But I do compliment you for holding the hearing and yield back the balance of my time.

Mr. STEARNS. I thank the gentleman. The gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman. Like everyone who was at the hearing yesterday, I was shocked by the testimony that we heard. We started out hearing testimony from families who have suffered the loss of their children to Ephedra, including the family of an athlete.

We also heard from scientific experts who are convinced that Ephedra consumption has overwhelming dangerous side effects, such as strokes and heart attacks. We then heard from the people in the industry who are manufacturing and selling so-called dietary supplements containing Ephedra.

It was stunning to hear the testimony because most of these individuals had no degree in pharmacy, no medicine degree, no college degree. They had high school degrees. And when we asked them what was in their dietary supplements, they had no idea what many of the ingredients were.

The way they figured out how to put the different herbs other elements in the supplements was that they looked at sheets that they got over the internet and other places. Now, I think most Americans assume that these so-called dietary supplements are safe because they are herbal.

In fact, I asked the lay witnesses about that, and they said, well, sure, they sell these supplements at our gyms. They sell these supplements at convenience stores, at 7-11s. And I myself am guilty of thinking from time to time before yesterday that these dietary supplements are safe because they contain herbs.

But what we realized with Ephedra at least is these herbs can be fatal. Now, the other thing that really concerned me yesterday was to hear the wide variety of opinion among the people who are manufacturing and distributing these dietary supplements.

They don't even have agreement as to who this supplement is safe to take. They did all admit that they now put on their bottles do not distribute to children under 18. And the reason that they put that they admitted is because several States now require that labeling.

Otherwise, I doubt that they would even place that on the bottle. But several of them said that Ephedra is counter-indicated for athletes. I guess that was probably their high school biology class that taught them that since that would be the advanced degree that they have.

But then others of the manufacturers said, no, they do not recommend these items for athletes. Dr. Coker who testified yesterday is in fact a medical doctor. He is a paid consultant to one of the companies, Cyadine, and not only is he a doctor, but a trainer. He recommends Ephedra for his athlete clients.

So as we can see there is a wide divergence of opinion as to whether or not this substance is safe. But yet at the same time there is mounting evidence that Ephedra can cause heart attack, stroke, and worse.

So, Mr. Chairman, I want to thank both you and Mr. Greenwood for convening this joint committee hearing. I think that this is an incredibly important issue, and as the sales of these so-called dietary supplements mushroom in this country, I think that our committees and this Congress need to take a long hard look at how we are regulating or not regulating the dietary supplement industry, because I think that things have changed dramatically in the roughly 10 years since Congress passed the legislation.

I think we need to revisit this for the health and safety of our constituents, and with that, I yield back the balance of my time.

Mr. STEARNS. I thank the gentlelady. The gentleman from Nebraska, Mr. Terry.

Mr. TERRY. I pass.

Mr. STEARNS. Okay. The gentleman from New Hampshire.

Mr. BASS. Thank you, Mr. Chairman. It was a very interesting hearing yesterday, and it will be equally interesting today. I want

to thank you both you and Mr. Greenwood for having this opportunity or giving us this opportunity to learn about this dietary supplement, which quite frankly I knew almost nothing about 24 hours ago.

We have heard from victims, and doctors, and manufacturers, and today we hear from regulators, and in effect, or in some respects, sports coaches, and sports individuals, and is a form of regulation.

But I think most interestingly is going to be the second panel today, where we hear from the government, and try to figure out how much they understand about this dietary supplement, and what their recommendations might be for any kind of policy initiative on the part of this committee and the Congress.

Clearly something has to be done, but like all issues, it is complicated, and it is not totally clear what our options are, but I believe that by the end of the day today that we will have a very clear idea as to what our options are, and how quickly or slowly we should proceed.

I want to thank you both for holding this joint hearing, and I look forward to hearing the testimony and I yield back.

Mr. STEARNS. I thank the gentleman, and we have also a Member of Congress from Colorado, Ms. Davis, who is welcomed. We welcome her to our committee this morning, joint committees. She is not a member of either subcommittee, but we enjoy her participation.

With that I will call the first panel forward. We have Mr. Robert Manfred, Junior, Executive Vice President, Labor Relations/Human Resources, of Major League Baseball; Mr. Eugene Orza, Associate General Counsel, The Major League Baseball Players Association; Mr. Adolpho A. Birch, III, Counsel for Labor Relations, The National Football League; Mr. Mike Helton, President, National Association for Stock Car Auto Racing; Mr. Donald Garber, Commissioner, Major League Soccer; and Professor Matt Mitten, Associate Dean for Academic Affairs, Marquette University Law School, Director, National Sports Law Institute, with Mr. Abe Frank, the National Collegiate Athletic Association.

So I welcome you folks this morning. You are aware that the committee is holding an investigative hearing, and when doing so, has had the practice of taking testimony under oath. Do you have any objection to testifying under oath?

[Chorus of no's.]

Mr. STEARNS. The Chair then advises you that under the rules of the House and the rules of the committee that you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony?

[Chorus of no's.]

Mr. STEARNS. In that case, if you would please rise and raise your right hand. I will swear you in.

[Witnesses sworn.]

Mr. STEARNS. You are now under oath, and you may now give, each of you, your 5 minute summary of your written statement, and Mr. Manfred, we will start with you.

TESTIMONY OF ROBERT D. MANFRED, JR., EXECUTIVE VICE PRESIDENT, LABOR RELATIONS/HUMAN RESOURCES, MAJOR LEAGUE BASEBALL; EUGENE D. ORZA, ASSOCIATE GENERAL COUNSEL, MAJOR LEAGUE BASEBALL PLAYERS ASSOCIATION; ADOLPHO A. BIRCH III, COUNSEL FOR LABOR RELATIONS, NATIONAL FOOTBALL LEAGUE; MIKE HELTON, PRESIDENT, NATIONAL ASSOCIATION FOR STOCK CAR AUTO RACING; DONALD P. GARBER, COMMISSIONER, MAJOR LEAGUE SOCCER; AND MATTHEW J. MITTEN, ASSOCIATE DEAN FOR ACADEMIC AFFAIRS, MARQUETTE UNIVERSITY LAW SCHOOL, DIRECTOR, NATIONAL SPORTS LAW INSTITUTE, THE NATIONAL COLLEGIATE ATHLETIC ASSOCIATION

Mr. MANFRED. Thank you. I would like to begin by thanking the committee for the opportunity to be here today. My name is Robert Manfred, and I am the Executive Vice President of Labor Relations and Human Resources in the Office of the Commissioner of Baseball.

In my role at the Office of the Commissioner, I am responsible for the day to day enforcement of our major league drug policy and a separate policy that applies to players in minor league baseball.

The major league drug program is the product of collective bargaining with the major league baseball players association, and the minor league program was unilaterally adopted by Commissioner Allan H. Selig before the 2001 playing season, and has been periodically amended since that time.

Several years ago the Commissioner directed those of us on his staff to develop a policy designed to eliminate the use of often dangerous performance enhancing substances in major league baseball and all of professional baseball.

The Commissioner's desire to eliminate the use of such substances was based not only on his concern for the integrity of the game, but also on a concern for the health and well-being of all professional baseball players, major league and minor league, as well as the young people in America who often see professional athletes as role models.

The Commissioner's directive was aimed not only at the anabolic androgenic steroids covered by Schedule III of the Code of Federal Regulations, but also certain substances sold as over the counter nutritional supplements.

In response to the Commissioner's directive, Major League Baseball has developed a three-pronged strategy for dealing with the problem of performance enhancing substances. The first prong of the strategy was to support increased Federal regulation of over the counter nutritional supplements.

On June 18, 2002, I had the privilege of testifying before the Senate Commerce Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, in support of the proposition that over the counter supplements should be more heavily regulated by the Federal Government.

I have provided a copy of that testimony to the committee. In addition, Commissioner Selig and I recently co-authored a law review article that will be published this fall by the Stanford Law and Policy Review advocating the need for legislative reform in the area of nutritional supplements.

Major League Baseball has consistently advocated additional regulation of nutritional supplements on the theory that certain supplements, including the subject of today's hearing, Ephedra, pose a health risk to professional athletes and on the theory that other supplements, including androstenedione, norandrostenedione, androstenediol, and norandrostenediol, have the same anabolic androgenic effects as substances currently on Schedule III.

The second prong of our strategy called for the education of professional baseball players. The Office of the Commissioner, along with the 30 major league clubs, and the Major League Baseball Players Association, have conducted a number of important educational programs.

Together with the MLBPA, the Office of the Commissioner funded the leading study by Harvard University on the effects of androstenedione. In addition, several years ago the Medical advisors to the Office of the Commissioner and the MLBPA jointly authored an educational pamphlet on steroids and nutritional supplements.

The pamphlet generally advises players to consult with a physician before using any nutritional supplement. That pamphlet also contained a warning with respect to the use of Ephedra.

It reads, "There has been a number of severe side effects reported related to the drug, including high blood pressure, rapid heart rate, seizures, strokes, heart attacks, and death. Ephedrine is also associated with physiological side effects, such as irritability, anxiety, tremors, paranoia, and in rare instances, a complete break with reality."

The third prong of the strategy involved the adoption of policies applicable to those who play professional baseball. As you are probably aware, the players in minor league baseball are not unionized. As a result the Commissioner was free to unilaterally adopt a drug policy applicable to those players.

As originally adopted the policy banned drugs of abuse, that is, illegal drugs, anabolic androgenic steroids, and the nutritional supplement, androstenedione. Based on subsequent developments, including the tragic death of Baltimore Oriole's pitcher, Steve Bechler, the policy was amended to ban the nutritional supplements norandrostenedione, androstenediol, norandrostenediol, and ephedrine.

Commissioner Selig has devoted extensive financial resources to the enforcement of our minor league program. Each year the Office of the Commissioner conducts over 5,000 tests on minor league players at the A, AA, and AAA level.

The testing is across the board, and unannounced, and all players are subject to at least two tests a year. Players who initially test positive receive individualized education and counseling. These players are then subject to serious disciplinary action for subsequent violations.

The testing regime covers drugs of abuse, steroids, as well as the banned nutritional supplements, including Ephedrine. The major league drug program is the product of bargaining with the MLBPA.

The program bans drugs of abuse, illegal drugs, and all anabolic androgenic steroids covered by Schedule III. The policy includes a significant testing component, and unlike the minor league pro-

gram, however, the major league program does not ban any over the counter supplements.

During negotiations with the MLBPA for a new agreement last summer the clubs did propose a ban on one over the counter supplement, androstenedione. The MLBPA's reaction to that proposal was firm and forceful. The Union would not agree to any ban on a substance that was available over the counter.

The MLBPA said it would not prohibit the use of a substance that could be purchased even by minors at any nutrition store. While there was no specific discussion of Ephedrine during the negotiations last summer, there was no mistake as to the MLBPA's position on over-the-counter supplements.

From Commissioner Selig's perspective the untimely death of Baltimore Oriole's pitcher Steve Bechler changed the world of baseball. In addition to amending the minor league drug program in the manner I have described above, Commissioner Selig directed me to begin conversations on the topic of Ephedra with the MLBPA.

In such discussions, I have made a number of suggestions as to how a ban on Ephedra could be integrated into the major league program.

Mr. STEARNS. Mr. Manfred, we just need you to summarize.

Mr. MANFRED. All right. To date the union has made no formal response. At the end of the day our position is that the issue of Ephedra should be dealt with as a matter of Federal regulation.

It is not an issue that is appropriately resolved in collective bargaining or easily resolved in collective bargaining and that because it involves the safety and health of professional athletes, as well as the public generally, we would urge the committee to regulate Ephedra in the same manner as substances on Schedule III, and to revisit the entire area of the regulation of nutritional supplements.

[The prepared statement of Robert D. Manfred, Jr. follows:]

PREPARED STATEMENT OF ROBERT D. MANFRED, JR., MAJOR LEAGUE BASEBALL
EXECUTIVE VICE PRESIDENT OF LABOR AND HUMAN RESOURCES

My name is Robert D. Manfred, Jr. and I am Executive Vice President of Labor Relations and Human Resources for the Office of the Commissioner of Baseball. In my role with the Office of the Commissioner, I am responsible for the day-to-day enforcement of Major League Baseball's Joint Drug Prevention and Treatment Program ("the Major League Drug Program") and Major League Baseball's Minor League Drug Prevention and Treatment Program ("the Minor League Drug Program") which are attached hereto as Exhibits 1 and 2, respectively. The Major League Drug Program is the product of collective bargaining between the thirty Major League Clubs and the Major League Baseball Players Association ("MLBPA"). The Minor League Drug Program was unilaterally adopted by Allan H. Selig, the Commissioner of Baseball, before the 2001 playing season and has been periodically amended since that time.

Several years ago, Commissioner Selig directed those of us on his staff to develop a policy designed to eliminate the use of often-dangerous, performance-enhancing substances in professional baseball. The Commissioner's desire to eliminate the use of such substances was based not only on his concern for the integrity of the game, but also on his concern for the health and well being of all professional baseball players, both Major League and Minor League, and young people who see professional athletes as role models. The Commissioner's directive was aimed at the anabolic androgenic steroids covered by Schedule III of the Code of Federal Regulations' Schedule of Controlled Substances ("Schedule III") as well as certain substances sold over-the-counter as nutritional supplements.

In response to the Commissioner's directive, Major League Baseball developed a three-pronged strategy for dealing with the problem of performance-enhancing sub-

stances. The first prong of the strategy was to support increased federal regulation of over-the-counter nutritional supplements. On June 18, 2002, I had the privilege of testifying before the Senate Commerce Subcommittee on Consumer Affairs, Foreign Commerce and Tourism in support of the proposition that over-the-counter nutritional supplements should be more heavily regulated. A copy of my testimony is attached hereto as Exhibit 3. In addition, Commissioner Selig and I recently co-authored a law review article that will be published this fall by the *Stanford Law and Policy Review* advocating the need for legislative reform in the area of nutritional supplements. A copy of that law review article is attached hereto as Exhibit 4.

Major League Baseball has consistently advocated additional regulation of nutritional supplements on the theory that certain supplements, including the subject of today's hearing, ephedrine, pose a health risk to professional athletes and on the theory that other supplements (including androstenedione, norandrostenedione, androstenediol and norandrostenediol) have the same anabolic androgenic effects as the substances included on Schedule III.

The second prong of this strategy called for the education of professional baseball players. The Office of the Commissioner along with the 30 Major League Clubs and the MLBPA have conducted a number of important educational programs. Together with the MLBPA, the Office of the Commissioner funded the leading study by Harvard University on the effects of androstenedione. In addition, several years ago, the medical advisors to the Office of the Commissioner and the MLBPA jointly authored an education pamphlet on steroids and nutritional supplements, which is attached hereto as part of Exhibit 3. That pamphlet contained the following warning with respect to the use of ephedrine:

There have been a number of severe side effects reported related to the drug, including high blood pressure, rapid heart rate, seizures, strokes, heart attacks, and death. Ephedrine is also associated with physiological side effects such as increased irritability, anxiety, tremors, paranoia and, in rare instances, a complete break with reality.

Steroids and Nutritional Supplements, p. 12.

The third prong of the strategy involved the adoption of policies applicable to those who play professional baseball. As you are probably aware, the players in Minor League Baseball are not unionized. As a result, the Commissioner was free to unilaterally adopt a drug policy applicable to Minor League players. As originally adopted, the policy banned drugs of abuse (*i.e.*, illegal drugs), anabolic androgenic steroids and the nutritional supplement, androstenedione. Based on subsequent developments, including the tragic death of Baltimore Orioles' pitcher Steve Bechler, the policy was amended to ban the nutritional supplements norandrostenedione, androstenediol, norandrostenediol and ephedrine.

Commissioner Selig has devoted extensive financial resources to the enforcement of the Minor League Drug Program. Each year, the Office of the Commissioner conducts over 5,000 tests of Minor League players in A, AA, and AAA leagues. The testing is across the board, unannounced and all players are subject to at least two tests per year. Players who test positive initially receive education and counseling. These players are then subject to serious disciplinary action for subsequent violations. The testing regime covers drugs of abuse, anabolic androgenic steroids, as well as the banned nutritional supplements, including products that contain ephedrine.

The Major League Drug Program is, of course, the product of collective bargaining with the MLBPA. The program bans drugs of abuse and all anabolic androgenic steroids covered by Schedule III. The policy also includes a significant testing component. Unlike the Minor League Drug Program, however, the Major League Program does not ban any over-the-counter supplements. In other words, under the Major League Drug Program players are allowed to use substances such as androstenedione and ephedrine.

During the negotiations with the MLBPA for a new agreement last summer, the Clubs did propose a ban on one over-the-counter supplement, androstenedione. The MLBPA's reaction to that proposal was firm and forceful: the union would not agree to any ban on a substance that was available over-the-counter. The MLBPA said it would not prohibit the use of a substance that could be purchased, even by minors, at any nutrition store. While there was no specific discussion of ephedrine during the negotiations last summer, there was no mistake as to the MLBPA's position on over-the-counter supplements.

From Commissioner Selig's perspective, the untimely death of Baltimore Orioles' pitcher Steve Bechler changed the world. In addition to amending the Minor League Drug Program in the manner described above, Commissioner Selig directed me to begin conversations on the topic of ephedrine with the MLBPA. In such discussions, I have made a number of suggestions as to how a ban on ephedrine could be inte-

grated into the Major League Drug Program. To date, the MLBPA has not made a formal, substantive response to those suggestions.

I have spent my entire professional career in the field of labor relations and, in my view, the system of collective bargaining created and fostered by the National Labor Relations Act is well-suited to address many problems. Unfortunately, the appropriate regulation of dangerous substances such as ephedrine is not one of those problems. My experience suggests that it is extremely difficult to convince a group of employees to agree to ban a substance that the Federal Government has, in essence, chosen not to regulate. As a result, Major League Baseball's official position is that ephedrine should be regulated by the Federal Government in the same manner as a controlled substance in order to protect the health and safety of our employees, as well as the public generally.

Ephedrine, however, is only the tip of the iceberg. In the wake of Steve Bechler's death, manufacturers of nutritional supplements have responded with new "ephedrine free" products. It remains to be seen what those products contain and whether they will turn out to be hazardous as well. Even more important, the youth of America has essentially unbridled access to substances which have the same purpose and effect as the anabolic androgenic steroids that are included on Schedule III. The substances include androstenedione, androstenediol, norandrostenedione, and norandrostenediol, collectively referred to as "precursors". Because of the problems associated with nutritional supplements generally, I, on behalf of Major League Baseball, urge you to undertake a broader reexamination of the insufficient regulatory framework created by the Dietary Supplement Health and Education Act.

Mr. STEARNS. Mr. Orza.

TESTIMONY OF EUGENE D. ORZA

Mr. ORZA. Thank you, Mr. Chairman, and members of the committee. I gather from your last comment that you would like me to summarize even more?

Mr. STEARNS. Well, we are just suggesting that everybody try to stay within 5 minutes. Obviously you can see that Mr. Manfred went over, but since we have a panel—

Mr. ORZA. I assure you that is uncommon in his case.

Mr. STEARNS. Okay.

Mr. ORZA. And I will do that. I will give a summary of my summary. My name is as you note Eugene Orza, and I am the Associate General Counsel of the Player's Association. I have been that for over 19 years now.

We, too, like you believe, for some time have done an overall legislative and regulatory reexamination of all dietary supplements, to include their composition, their marketing, their labeling, and most importantly their safety, as appropriate.

Baseball players, just like the overwhelming majority of their fellow American citizens, look to the Federal Government as the ultimate arbiter of the degree, if any, to which ingestible substances require regulation.

And consistent with our view of the Federal Government's role and responsibility in this area, we would wholeheartedly support and embrace a decision by the Congress, the FDA, or by any other arm of the Federal Government in the business of determining what is safe and what is not safe, and to more strictly regulate, to control, or even ban, any specific dietary supplement that the available science suggests to this Congress should be more strictly regulated, controlled, or even banned.

The position of the Player's Association has also been, and continues to be, that players should not be prohibited from using any substances that the United States government has effectively de-

terminated are not unsafe for consumption by other American consumers.

We recognize that the government's decision thus far to refrain from taking any significant action relating to Ephedra appears to be based at least to some degree on what was earlier at least its inability to forge an appropriate consensus on exactly what the science shows with those who advocate stricter control, and have been unable to change the current governmental order of things.

The passage of time in the Ephedra debate seems to have produced large numbers of people who have at least come to believe, probably erroneously, that it was their safe use of Ephedra that enabled them to control or reduce their weight, and that has probably only complicated matters for those who are seeking to change.

But I wish to emphasize this, and emphasize it strongly. The players are not asking you to keep Ephedra-based supplements freely available on the market as they now are. They are asking instead for the Congress' best judgment as to whether that should continue to be the case.

They will happily abide any authoritative decision by this Congress that your deliberations and your processes produce. None of this is to suggest an absence of communication on the subject of this with our members, often jointly with the clubs, in pamphlets, memorandums, and meetings, and Mr. Manfred has described that to some extent.

And over the past several years the association has warned its adult players about what appear to be the dangers lurking with the use and especially the misuse of Ephedra-based supplements, and all of this is described more fully in my full statement submitted earlier to the committee.

Even before Steve Bechler's tragic passing, we had sought to encourage the Congress and the Federal Government to reexamine both the safety and the adequacy of the current Federal regulatory structure for dietary supplements, and the sufficiency of existing law.

We have thought, for example, that while the law may be appropriate for the vast majority of vitamins, minerals, and some herbal-based products, there are some supplements which are not naturally or traditionally part of most diets, and seem to be taken more for their presumed, and I might add artfully touted, pharmacological benefit, than for any nutritional value that they may purport to have.

Perhaps consideration should and can be given to treating these sorts of products different from, for example, the way that Vitamin C, Vitamin E, or folic acid should be treated. In the end, however, we believe that governing scientific determinations about the safety and efficacy of ingestible substances are not only best left to the governing Federal institutions and agencies, but are entrusted to them by the American people, who look to the government and rely upon the government for the neutral, unbiased science they need and deserve.

Viewed from the broad historical perspective government agencies, whose vision is not colored by the profit motive, have shown a commendable capacity to make findings based on the totality of

the evidence, medical information and research, and to ensure their conclusions are based on fact and not self-interest.

And the phrase, the players, just like me, and everyone I know, look to the Federal Government, and not interest groups or newspapers, and certainly not advertisers with their promises of a new and improved you, to tell the country what should and should not be regulated, controlled, or banned.

And as I said earlier, whatever the Congress decides, we will happily abide. Mr. Chairman and members of the committee, thank you for that opportunity.

[The prepared statement of Eugene D. Orza follows:]

PREPARED STATEMENT OF EUGENE D. ORZA, MAJOR LEAGUE BASEBALL PLAYERS ASSOCIATION

Mr. Chairman and Members of the Committee: My name is Gene Orza, and I serve as Associate General Counsel of the Major League Baseball Players Association. The Association is, as you know, the exclusive collective bargaining representative of all major league baseball players, and I am pleased to appear on their behalf today in response to the Subcommittees' invitation to testify.

The MLBPA understands and appreciates the Subcommittees' interest and concern about the use of dietary supplement products containing ephedra. As indicated in our submission to the full House Commerce Committee on April 15, 2003, we have for some time believed that an overall legislative and regulatory reexamination of all dietary supplements, to include their composition, their marketing and labeling, and their safety, has been appropriate. Baseball players, just like the overwhelming majority of their fellow citizens, look to the federal government as the ultimate arbiter of the degree, if any, to which ingestible substances require regulation. Consistent with our view of the federal government's role in the determination of what is safe and not safe, we would, therefore, wholeheartedly support and embrace a decision by Congress, the Food and Drug Administration, or by any other arm of the federal government in the business of determining what is safe and not safe, to more strictly regulate or even ban any specific dietary supplement that the available science suggests to the Congress should be more strictly regulated or banned.

The position of the Players Association has long been that players should not be prohibited from using any substances that the United States government has effectively determined are not unsafe for consumption by other American consumers. As I am sure you know, the issue of how best to regulate ephedra-based products is not new to this Committee, the Congress as a whole, or the FDA. In fact, I believe the debate actually predates Congressional consideration and passage of the Dietary Supplement Health and Education Act in 1994. Over the ensuing decade, the government's decision to refrain from taking any significant action relating to ephedra appears to be based, at least to some degree, on the inability to forge an appropriate consensus on exactly what the science shows, with those who advocate stricter control unable to change the governmental order of things when it comes to dietary supplements. The task has only been more complicated by the passage of time, which has produced large numbers of people who have at least come to believe that it was their safe use of ephedra that enabled them to control or reduce their weight.

The MLBPA and Major League Baseball have a four-person Health Policy Advisory Committee, staffed by a medical and legal representative of the Players and Clubs. The duties of the Committee are wide-ranging, and include the review of medical literature pertinent to players. Among other things, the Committee, and principally its medical representatives, has reviewed on an ongoing basis scientific literature related to the health effects of a number of dietary supplements, not just ephedra. In fact, it was on HPAC's recommendation that the Players Association and the Clubs jointly funded a study of androstenedione, conducted by two distinguished scientists at Massachusetts General Hospital, that represents a major contribution to the scientific literature on the substance and for which contribution, frankly, the players and clubs deserve commendation. I believe the committee has been provided with a copy of the study.

For the past three Spring Trainings, dating from 2001, HPAC has caused to be distributed to players a pamphlet, which HPAC authored, concerning nutritional supplements. The very first paragraph of that document is instructive of the Committee's approach to this matter. It reads:

No pamphlet... can serve as a substitute for personalized professional consultation. Consequently, no player should take any substances reported or claimed to improve training capacity, to increase strength and endurance, or to improve performance without first consulting his personal physician or a physician knowledgeable in these areas.

The pamphlet contains a specific section on "Ephedrine", and includes the following language:

There have been a number of severe side effects reported related to the drug, including high blood pressure, rapid heart rate, seizures, strokes, heart attacks, and death. Ephedrine is also associated with psychological side effects such as increased irritability, anxiety, tremors, paranoia and, in rare instances, a complete break with reality. The psychological effects of the drug often severely impair performance.

With the onset of litigation involving the death of Steve Bechler, it is perhaps best that not too much be said about it at this time. All of us in baseball, players and clubs alike, were and remain deeply saddened at Steve's passing. We can say this much. Shortly after Steve's death, we sent a memorandum to all players, notifying them that we were monitoring the situation, and advising the players that the Department of Health and Human Services had taken action to alert possible users of ephedra to risks potentially associated with use of the product. We passed along the Department's warning to athletes and others who engage in strenuous physical activities, and we reiterated our discouragement of the use of ephedra-based products.

Then, on March 14, 2003, we sent another memorandum to the players following the release of the autopsy report on Steve. We advised the players that while the report concluded that Steve's use of Xenadrine was not the sole cause of his death, it also concluded it was a contributing cause of it, and players therefore should be extremely reluctant to use ephedra-based products.

In addition, Don Fehr, the Association's Executive Director, annually undertakes a tour of all spring training camps. In 2003, he made sure that a portion of these meetings—which are intended to encompass the vast sweep of issues that continually confront the union—was devoted to ephedra. He emphasized, during his meetings, that under the framework of the Dietary Supplement Health and Education Act, the legality of a dietary supplement should not be construed to be the equivalent of a governmental determination of its safety; that the law was designed to block the sale of products found to be unsafe after their sale, and not to allow the sale of products only if prior to sale they were determined by the FDA to be safe; that the Association has always felt that any supplement product should only be taken after consultation with a physician; and, that every player should make sure they read supplement labels and, if they found the label confusing, to talk to someone who could explain it. Don actually read to all the players parts of the warning label on Xenadrine, including the admonition to "consult a physician or licensed health professional before using" the product; not to use the product if taking any other drugs containing ephedrine or pseudoephedrine, or other weight control products; and, importantly, its warning that recommended dosages should not be exceeded, and that doing so "may cause serious adverse health effects, including heart attack and stroke." Don concluded his remarks, in the meetings I and others observed, by encouraging the players once again to refrain from using ephedra-based supplements pending such additional scientific evidence as might come out of the ongoing governmental review.

And finally, just a couple of weeks ago, at a meeting of HPAC, the Association and Clubs agreed that they would recast and reemphasize the warnings given in its pamphlet on supplements, and to urge the players, and indeed everyone in the baseball community, to be extremely cautious about ephedra-based products in the face of that same ongoing governmental review of the adequacy of the science that makes ephedra-based products as freely saleable as they are.

The MLBPA has been encouraging the Congress and the federal government to reexamine both the safety and adequacy of the current federal regulatory structure for dietary supplements, and the sufficiency of existing law, well before Steve Bechler's tragic passing. We have long thought that there is a compelling argument that while the law may be appropriate for the vast majority of vitamins, minerals and herbal-based products, there are some substances, and their number seems to increase weekly, which are not naturally or traditionally part of most diets and are taken more for their presumed and artfully touted pharmacological benefit than for any nutritional value they may indeed have. Perhaps consideration should be given to treating these sorts of products different from, for example, the way the regulatory scheme should treat Vitamin C or folic acid.

In the end, however, we believe that scientific determinations about the safety and efficacy of ingestible ingredients, whether they are nutritional supplements or other types of food, are not only best left to the appropriate federal regulatory agencies, but are entrusted to them by the American people, who look to the government and rely on the government for the neutral, unbiased science they need and deserve. Viewed from the broad historical perspective, neutral government agencies—whose vision is not colored by the profit motive—have shown a commendable capacity to make findings based on the totality of the evidence, medical information and research, and to ensure that conclusions are based on fact and not self-interest. In a phrase, the Players—just like me and everyone I know—look to the federal government, and not advertisers, interest groups, or newspapers, to tell the country what should and should not be regulated, controlled, or banned.

Finally, let me address an issue that is always raised in this context—what message is our decision to rely upon the federal government's determination of what is and is not freely available as a consumable sending to young people who are playing baseball or any other sport and may be dreaming of a career in the big leagues? Frankly, it is the same message we send to today's Players. Play to the best of your ability, but not at the price of your health. Products that have not withstood the test of time and are accompanied by clarion calls of "a new and improved you" should be viewed skeptically—even if the government allows them to be freely sold. And remember just as there is a difference in all players, so that the efficacy of a product for one person might not be beneficial for another, there is also a profound difference between the use of any product and its misuse.

Mr. Chairman, and members of the Committee, thank you again for the opportunity to share some of our views about ephedra, and I would be happy to try to answer any questions that you may have.

Mr. STEARNS. I thank the gentleman.

Mr. Birch.

TESTIMONY OF ADOLPHO A. BIRCH III

Mr. BIRCH. Thank you. First of all, on behalf of the National Football League, we would like to thank you for inviting us to participate today. I think that it is important and we appreciate the opportunity to share our perspective on Ephedra in the athletic environment.

If it would please the committee, I would like to kind of focus on three areas, the first of which would be the development of our steroid policy, followed by the development of our Ephedrine policy and then last our views on regulation of Ephedrine and other substances.

The NFL and the NFL Players Association have long been concerned with eliminating the use of anabolic steroids and other performance enhancing substances from our game. In that regard, we are guided primarily by three principles.

The first of which is that the use of performance enhancing substances threatens the integrity of the competition on our field. Our game depends upon maintaining a level playing field, and to the extent that some players are permitted to gain an advantage through the use of certain substances casts doubt on the fairness and legitimacy of our games.

Second, the altering—or excuse me, allowing the use of certain substances without penalty would force other players to feel compelled to use those same products, whether or not they feel that they have a benefit, in order to compete with the players who are using them.

And, of course, this applies not only to anabolic steroids, but also to Ephedrine and other stimulants which some players feel gives them a boost or an edge in competition. Second, we are concerned about the players' safety and welfare. Our players obviously accept

a certain degree of risk to play our game, but the types of substances that are becoming available for use without testing or regulation constitute in our opinion an undue risk and a risk of danger, of illness, and death.

Finally, we understand and accept our obligation as role models for both the youth generally and for young athletes. It goes without saying that players who utilize these substances give young athletes the opinion that it is okay and that it gives them the desire to use those substances as well.

We feel very strongly that that is not the type of consequence that we want to occur with respect to our players. Keeping those players in mind, we developed in 1989 a policy of testing, education, and discipline, the key provisions of which are as follows.

First, we have unannounced annual and random testing of all players both in and out of season. Second, we have a prohibited list which contains over 70 substances, including anabolic steroids, precursors, growth hormones, and stimulants.

Third, we have a mandatory four game suspension without pay upon first violation of the policy. And finally we have a strict liability standard for positive test results, and essentially that means that the players are responsible for what goes into their bodies, and positive tests are not excused because of an inadvertent use, or because a player was unaware that he was taking a banned substance.

Turning more specifically to our Ephedrine policy, we began to develop that policy around 1998 or 1999, and that was as a result of a few reported incidents involving NFL players and the use of Ephedrine.

In one such case a player had a seizure on an airplane, and that ultimately required medical intervention to restore his heart rhythm. After investigation and consultation with our medical advisory board at the time, we determined that a health alert was important.

So we issued that health alert and began a player education program. Following the death of Corey Stringer in the summer of 2001, we revisited the entire issue about training camp conditions and policies.

What we found was that there was certainly a possible link between Ephedrine and some heat illness related incidents in training camp. As a result of all of that investigation, we ultimately said that the risk of Ephedrine certainly outweighed any of its purported therapeutic use.

And at that time the league and players association agreed that a ban was important and necessary, and in September of that year we did announce an immediate ban of Ephedrine and several other products, and ultimately testing followed, and now discipline has followed, and it runs under the same disciplinary structure and testing structure as our other steroids.

With respect to regulation, we are very concerned about this issue for three basic reasons. Our population is unique among supplement users. As world-class athletes, we are concerned that they have more awareness of these supplements, but more importantly there is more pressure to use those supplements, because they are

enodated with material, free product, advice, and other forms of enticement to utilize supplements.

Additionally, under the current framework there is no required pre-approval testing or regulation to determine not only the safety or efficacy of the products, but also whether the labels are accurate.

And as such our players are finding it increasingly difficult to make sure that what they are taking does not fall inside our prohibited list. And finally obviously we understand our obligation as role models, and we wish that regulation in that regard would assist us in helping to prevent young athletes and youth from feeling that they needed to take those supplements.

So as a conclusion, we feel that decisive action on the of this committee and on the part of the Federal Government generally would be very critical to us in the continued effectiveness of our policy, as well as the health and safety of our players. Thank you.

[The prepared statement of Adolpho A. Birch III follows:]

PREPARED STATEMENT OF ADOLPHO A. BIRCH III, NATIONAL FOOTBALL LEAGUE

The National Football League would like to thank the Subcommittees for inviting us to participate in this hearing on ephedrine. We greatly appreciate the opportunity to share with you our thoughts and concerns on ephedrine and related products in the athletic environment.

DEVELOPMENT OF THE NFL'S STEROID POLICY

The National Football League and NFL Players Association have long been committed to ensuring that our sport is not tarnished by the influence of steroids and other performance-enhancing substances. We are guided in this respect by three principles:

First, these substances threaten the fairness and integrity of the athletic competition on the playing field and could potentially distort the results of game and League standings. Moreover, the use of certain substances by some players without consequence might lead other players to believe that they must use them as well in order to remain competitive. This concern arises not only with respect to steroids, but also with respect to ephedrine and other stimulants, which some players believe will provide a boost or "edge" in competition.

Second, the League has serious concerns about the adverse health effects of these substances on our players. There is a growing body of medical literature linking their use to a number of physiological, psychological, orthopedic, reproductive and other serious health problems.

Third, the NFL takes very seriously its role in educating and providing guidance to young athletes and youth generally. When young athletes see players that they admire using these substances, their desire to use such products increases dramatically. When combined with their still-developing judgment, young athletes face even higher risks than professional athletes. As role models, the NFL and its players must be concerned with such unintended consequences.

Adhering to these principles, in 1989 the NFL became the first professional league to implement a comprehensive program of steroid testing, discipline and education. The key provisions of our policy are:

- Unannounced annual and random testing of all players both in and out of season;
- A list of more than 70 prohibited substances including anabolic steroids, steroid precursors, growth hormones and stimulants;
- Mandatory 4-game suspension without pay upon first violation; and
- Strict liability for players who test positive—violations will not be excused because a player was unaware that a product contained a banned substance.

The consistent application of these core tenets has resulted in the NFL's policy being considered the most effective in professional sports.

EPHEDRINE POLICY

In late 1999, the League received reports from Clubs of incidents involving the use of ephedrine. In one case, a player who had apparently used ephedrine had a seizure that required medical intervention. Following that incident, our medical advisory board began to review the available medical and scientific literature on

ephedrine. Based on that initial review, we issued a health warning on ephedrine during the 2000 season and developed an educational program to provide more information.

In July 2001, following the tragic death of one of our players, we undertook a comprehensive review of the potential links between ephedrine use and heat illness, which is a focus of NFL Clubs during preseason training camp conditions. From that investigation we concluded that the risks of ephedrine outweighed its uncertain therapeutic benefit and that swift action was needed to protect the health and safety of our players and the competitive integrity of NFL football.

As a result, on September 26, 2001, the NFL became the first professional sports league to ban the use of ephedrine and other related stimulants. (A press release announcing the ban is attached.) After implementing an extensive player education program and resolving a number of logistical issues, we began testing for these substances during the 2002 preseason. Players testing positive for ephedrine are now subject to the same discipline as those testing positive for any other banned substance.

EPHEDRINE AND DIETARY SUPPLEMENT REGULATION

As an organization that employs world-class professional athletes, the NFL is very concerned with dietary supplements and their regulation. In our view, athletes represent a special category of potential supplement users. Because their success is directly correlated to physical ability and conditioning, athletes are generally more sensitive to issues regarding health and fitness. Unfortunately, they are also at greater risk because of the substantial pressure to use supplements as a part of their training regimen.

Over the past decade, the number of products claiming to provide energy, rapid recovery and dramatic weight loss has skyrocketed. Under current federal legislation, so-called "dietary supplements" containing ephedrine and other stimulants can be manufactured and marketed without any effective prior research, approvals or regulation. Scientific research has shown that these stimulants can pose significant health risks, particularly among athletes engaged in strenuous activity. Equally important, basic safeguards such as testing and labeling are not adequate to guarantee that a particular product actually contains only the ingredients listed on its label.

The cornerstone of the NFL's steroid policy is that players are responsible for what goes into their bodies. Given the deficiencies in labeling practices, however, it has become increasingly difficult for players to determine which "dietary supplements" are free of ephedrine and other prohibited substances. Anecdotal evidence suggests that a significant percentage of players who have tested positive for ephedrine did so through the inadvertent use of a seemingly harmless "dietary supplement."

By taking decisive action, Congress can address many of the concerns related to the use of ephedrine by its constituency. The NFL feels strongly that governmental leadership is critical to the continued effectiveness of our steroid policy, as well as to the health and safety of the general public.

Mr. STEARNS. I thank the gentleman.
Mr. Helton.

TESTIMONY OF MIKE HELTON

Mr. HELTON. Chairman Stearns, Chairman Greenwood, and subcommittee members, we appreciate the opportunity to appear before you today on this issue, and my submitted testimony covers NASCAR's continuing commitment to safety as impacted by the recent focus on the use of Ephedrine by athletes. So I will quickly summarize.

First, let me provide some background on NASCAR because our structure is unique among major sports, and NASCAR's approach to its substance abuse issues is tailored more to that structure. William H.G. France founded NASCAR in 1948 to organize and promote stock car racing. NASCAR is a private company, and continues to be owned and operated by the France family primarily from its headquarters in Daytona Beach, Florida.

William C. France is our chairman and CEO today, and I am the President of NASCAR and report directly to Mr. France. I have served in this role since November 2000, and prior to that I was the Senior Vice President and Chief Operating Officer for NASCAR.

Throughout my career with NASCAR, I have been directly involved in the supervision of NASCAR racing competition and the competitors. Our entire industry takes safety very seriously. A driver's life depends on his own ability to drive unimpaired and with great skill.

His life depends equally, if not more, on the ability of his co-drivers on the track to do the same thing. At each of the races in NASCAR's top three series, as well as in all of our regional touring series, NASCAR officials work side-by-side with our competitors on a regular basis.

Because of the close personal contact throughout the course of each event, and our competitors natural dependence on each other's abilities. Our officials are in a position that is unique among all sports officials, and when it comes to driver impairment, there are few if any secrets in our garage areas or on pit road.

To emphasize the critical importance of a substance-free sport, in 1988, NASCAR created its substance abuse policy. The policy provides for testing under reasonable suspicion, an approach that is well suited to our sport because of the close and continuing contact between our officials and our competitors.

And since the inception of its policy, NASCAR has screened and will continue to screen for Ephedrine at the standard testing level of 10,000 nanograms per milliliter. To date no test has revealed the presence of Ephedrine above that level.

As a result of recent events, our focus on Ephedrine has been sharpened. We immediately undertook an internal educational process to learn more in-depth about the risks of Ephedrine-containing products, and as part of that process, we contacted other sports leagues and consulted with our long-time scientific advisor about the facts of Ephedrine use and abuse.

Early in April 2003, we issued a written medical advisory to all of our officials, drivers, crew members, and competitors, stating that all NASCAR participants should seek guidance from their individual physicians prior to taking any supplement product labeled as containing Ephedra or Ephedrine.

NASCAR will continue to monitor developments in this important area through published medical literature and regulatory statements. At some point it may be appropriate to make our policy more specific with respect to the use of Ephedra-containing products.

Whatever NASCAR's decision in this regard may be, its first and foremost principle will be the safety and protection of our competitors and fans, and I will be happy to take questions later.

[The prepared statement of Mike Helton follows:]

PREPARED STATEMENT OF MIKE HELTON, PRESIDENT, NASCAR

Chairman Stearns and Chairman Greenwood, Ranking members Schakowsky and Deutsch, subcommittee members, I appreciate the opportunity to appear before you today on this important issue. My testimony will cover NASCAR's continuing commitment to safety as impacted by the recent focus on the use of ephedra/ephedrine

by athletes. I will provide information on the actions NASCAR has taken since the increase earlier this year in everyone's awareness of the dangers regarding the use of ephedra-containing or ephedrine-containing products, NASCAR's efforts to make its competitors and officials aware of the recent developments in this area, and our continuing commitment to monitor scientific and regulatory developments regarding the use of ephedra/ephedrine.

First, however, let me provide some background on NASCAR, because our structure is unique among the major sports, and NASCAR's approach to substance abuse issues is tailored to that structure.

William H.G. France founded NASCAR in 1948 to organize and promote stock-car racing. NASCAR, a private company, continues to be owned and operated by the France family, primarily from its headquarters in Daytona Beach, Florida. William C. France is the chairman of NASCAR. I am the president of NASCAR and report directly to Mr. France. I have served in this role since November 2000. Prior to that I was senior vice president and chief operating officer for NASCAR. Throughout most of my career with NASCAR, I have been directly involved in the supervision of NASCAR racing competition and competitors.

NASCAR is a sanctioning body for stock car racing. Our role is to sanction official NASCAR races, establish and enforce rules for those races, monitor the distribution of prize monies, and maintain a points system designed to determine annual championships in our various divisions.

NASCAR sanctions over 1,750 races annually in 12 different divisions, in 37 states. NASCAR-sanctioned racing runs the gamut, from weekly racing at small dirt tracks to regional touring series, to our three top-tier series. NASCAR's three highest-level series are national in scope. They are the NASCAR Winston Cup Series (which next year will become the NASCAR Nextel Series), the NASCAR Busch Series, Grand National Division, and the NASCAR Craftsman Truck Series.

Our drivers and their crew members are independent contractors, which makes NASCAR's structure somewhat unique in sports. In order to officiate or compete in a NASCAR-sanctioned event, an individual must apply for a license on an annual basis, and he or she must maintain that license in good standing throughout the year. To do so, all officials and competitors must abide by NASCAR's rules and procedures. When NASCAR makes a change in its rules or policies, all of these individuals are directly affected by it.

Our entire industry takes safety seriously. A driver's life depends on his own ability to drive unimpaired and with great skill. His life depends equally if not more on the ability of his co-drivers on the track to do the same thing. No driver, crew member or official wants to compete with another competitor who is not at the top of his game.

At each of the races in NASCAR's three top series, as well as in all of our regional touring series, NASCAR officials work side by side with our competitors on a regular basis. All of us arrive at the track by Friday of a race weekend, and for the next three days we share the restricted pit and garage areas, where the competitors prepare for the race while we literally look over their shoulders.

Because of the close personal contact throughout the course of each Event, and our competitors' natural dependence on each other's abilities, our officials are in a position that is unique among all sports officials. We are able to observe closely the conduct and condition of our competitors over extended periods of time. We are immediately available to any competitor who has a concern about the health of another competitor. When it comes to driver impairment, there are few if any secrets in the garage and pit area. This has been our environment for decades, and as a result we have a significant degree of confidence that if one of our athletes is or might be impaired as a result of substance abuse, we will observe or hear of it.

To emphasize the critical importance of a substance-free sport, in 1988 NASCAR created its Substance Abuse Policy. At this point, each person who competes in NASCAR-sanctioned events must review the Policy, and he must sign an acknowledgement that he has read the Policy. Of course, any use, possession, purchase or sale of illegal drugs is strictly prohibited by the Policy. But NASCAR's Policy goes further. It permits NASCAR to ban any substance, or the use of any substance, even if legal or medically indicated, that may affect adversely the safety and well being of competitors, officials and/or spectators or the performance of competitors or officials at a NASCAR event. As a result, in connection with any urine drug testing, since the inception of its policy NASCAR has screened, and will continue to screen, for ephedrine at standard testing levels (10,000 ng per ml). To date, no test has revealed the presence of ephedrine above that level.

The Policy provides for testing under reasonable suspicion, an approach that is well-suited to our sport because of the close and continuing contact between our officials and our competitors that I described above. If anyone violates the Policy, they

are subject to random testing thereafter. Fortunately, because our competitors are keenly aware of the dangers of substance abuse, at the highest levels of our sport we have rarely had to invoke the Substance Abuse Policy.

As noted above, NASCAR has monitored ephedrine levels in drug tests performed on competitors. As a result of recent events, of course, our focus has been sharpened. What has NASCAR done in 2003 with respect to the ephedrine/ephedra issue? Several things:

- We immediately undertook an internal educational process, to learn more in depth about the risks of ephedra-containing products. As part of that process, we contacted other sports leagues to obtain useful information and relevant policies.
- As part of our educational process, we consulted, and continue to consult, with our longtime scientific advisor, a highly-regarded, Board-certified forensic toxicologist, specializing in the field of athletics, about the facts of ephedra/ephedrine use and abuse.
- In early April 2003, we issued a written medical advisory to all of our drivers, their crew chiefs, and competitors in all twelve of NASCAR's racing divisions, from the NASCAR Winston Cup Series to the Weekly Racing Series. The same advisory went to all of our officials. That advisory informed all of our competitors of the principal conclusions of the February 28, 2003 Rand Study. We advised them that, in light of this and other studies, "all NASCAR participants [should] seek guidance from their individual physician prior to taking any supplement product labeled as containing ephedra/ephedrine."
- We are continuing to monitor, with our outside advisor, scientific developments in this important area.

Ephedra/ephedrine may be a useful product in many settings. None of us, however, including our sponsors, is interested in seeing it abused or used in an improper manner in NASCAR-sanctioned races. Our Substance Abuse Policy provides NASCAR with the flexibility to react to situations such as this one. Our commitment to safety provides NASCAR with the incentive to minimize the risk of danger from ephedra/ephedrine abuse.

NASCAR will continue to monitor developments in this important area through published medical literature and regulatory statements. At some point, it may be appropriate to make our Policy more specific with respect to use of ephedra-containing products. Whatever NASCAR's decision in this regard may be, its first and foremost principle will be the safety and protection of our competitors and our fans.

Mr. STEARNS. I thank the gentleman.

Mr. Garber.

TESTIMONY OF DONALD P. GARBER

Mr. GARBER. Thank you, Mr. Chairman, and members of the committee, for providing me with the opportunity to appear here today and address issues related to Ephedra-containing dietary supplements.

My name is Don Garber, and I am the Commissioner of Major League Soccer. I also serve on the executive committee of the United States Soccer Federation, which is the local governing body for our sport, with our responsibility to represent both men's and women's professional soccer in the United States.

By way of introduction, MLS is America's top men's professional soccer league. We are a new league and we are currently in the middle of our eighth season. My goal today is to assist the committee with its task by providing the following information.

First, our policy concerning our player's use of Ephedra-containing supplements, the rationale for creating this policy, and how we administer the policy. Major League Soccer prohibits the use of drugs of abuse and performance enhancing substances, including Ephedra, and I am proud to say that we have been banning Ephedra since 1999, and we were the first professional sports league to do so.

In conjunction with our prohibiting of these substances, we also impose year around random drug testing on our entire player pool. MLS, as the professional soccer league here in the United States, is governed by an organization called the Federation Internationale de Football Association, or FIFA, which is the world governing body for soccer.

In this regard, MLS has adopted FIFA's list of prohibited substances, which is identical to the banned substance list of the International Olympic Committee, or the IOC. MLS's testing panel follows the IOC guidelines, and either meets or exceeds standards set by other major professional sports leagues and the Department of Transportation.

Following the examples set by the IOC and FIFA, MLS classifies Ephedra as a performance-enhancing substance, and as such, as stated, we prohibit its use. MLS has banned drugs of abuse and performance enhancing substances, including Ephedra, for a number of reasons.

First and foremost, we are concerned about the health and the welfare of our players and their families. We take this responsibility very seriously, and in crafting policies regarding player welfare, we reviewed extensive information regarding the adverse health effects caused by the use and abuse of illegal drugs, steroids, and related substances.

Second, MLS believes that it is critically important for our players to serve as role models worthy of emulation by our fans. With more than 20 million players participating in this sport of soccer, we are the largest organized participatory sport in this country.

We also believe that soccer is the gateway to a new America, serving as the common denominator for the millions of immigrants who now call our great country home. This convergence of youth and ethnicity that uniquely comes together through soccer provides our league with a tremendous opportunity and responsibility to positively influence the behavior of a large and rapidly growing segment of our population.

As a professional sports league, we understand and we cherish this responsibility, and have created a drug education awareness and intervention program that we believe sets the highest standards for our players, and delivers the appropriate message to our young and our diverse fan base.

Third, soccer is the world's game, and our players are often summoned to compete in international competitions, like the World Cup and the Olympics, administered respectively by FIFA and the IOC, and as such our players and our league are determined that it is very logical to align ourselves with the doping policies of these organizations.

Finally, we believe that the use of performance enhancing substances compromises the integrity of professional sports. Athletes desire and wholeheartedly deserve a level playing field, where they can honorably compete to be at the very best, and to be at the highest level.

There is simply no room for cheaters in sports, and as our young league begins to establish its history, refused to face a future with the performance of our players, or the integrity of the world's most popular sport, is tarnished in any way.

When we were formed in 1996, we had the opportunity to take a leadership role in the development of a comprehensive and forward-thinking substance abuse and behavioral health program.

We have our four-pronged approach with education, prevention, assessment, and intervention, with the most important part of the program being education.

Each preseason and at times throughout the season, we randomly test our players, and we educate them on a wide variety of topics, from the perils of drinking and driving, as well as the use of club drugs and the importance of safe sex, and very importantly with the issue in the incident involving Steve Bechler, our players were educated as to the reported dangers involving the use of Ephedra-containing supplements.

As previously stated to wrap up a major component, the component of our program consists of that random drug testing of our players. If a player tests positive for a prohibitive substance under the direction of a third-party, we mandate counseling, and after counseling comes disciplinary action, and perhaps termination, and the termination of a player's contract.

However, and very importantly, the main focus of our program is to identify players with a substance abuse problem, and to provide them with assistance. Beyond these basic components, players and their families are encouraged to take advantage of a hotline that encourages them to seek counseling and referral for any substance or behavioral health issue.

Ultimately, we believe that the key to our program is to remain proactive, and our continual goal with the program is to prevent tragedies rather than to react to them. Once again, thank you for allowing me the opportunity to testify before you today. The entire United States soccer community appreciates the committee's diligence in investigating this topic.

[The prepared statement of Donald P. Garber follows:]

PREPARED STATEMENT OF DONALD P. GARBER, COMMISSIONER, MAJOR LEAGUE SOCCER

Mr. Chairman and members of the Committees, thank you for providing me with the opportunity to appear here today and address issues relating to Ephedra-containing dietary supplements.

My name is Don Garber and I am the Commissioner of Major League Soccer ("MLS"). By way of introduction, MLS is the United States' ten-team Division I outdoor men's professional soccer league. MLS is currently in the middle of its eighth season.

My goal today is to assist the Committee with its task by providing the following information: (1) The MLS policy concerning its players' use of Ephedra-containing supplements; (2) Our rationale for creating this policy; and (3) How MLS administers the policy.

1. MLS' Ephedra Policy

Major League Soccer prohibits the use of drugs of abuse and performance enhancing substances, including Ephedra. In conjunction with its prohibition, MLS imposes random drug testing on its entire player pool. Players are subject to year round testing.

MLS, through its local governing body the United States Soccer Federation, is governed by the Fédération Internationale de Football Association ("FIFA"), the world governing body for soccer. In this regard, MLS has adopted FIFA's list of prohibited substances which is identical to the banned substance list of the International Olympic Committee ("IOC"). MLS' testing panel follows IOC guidelines and either meets or exceeds standards set by other major professional sports leagues and

the Department of Transportation. To my knowledge, MLS was the first major professional sports league in the United States to ban Ephedra.

Following the examples set by the IOC and FIFA, MLS classifies Ephedra as a performance enhancing substance. Absent compelling scientific evidence to the contrary, MLS will not reclassify Ephedra.

2. MLS' Rationale for Prohibiting Drugs of Abuse and Performance Enhancing Substances Including Ephedra

Major League Soccer has banned drugs of abuse and performance enhancing substances, including Ephedra, for a number of reasons. First and foremost, MLS is concerned about the health and welfare of its players and their families. The reasoning is simple. Our players are our most important asset. To achieve our stated goal of being one of the top soccer leagues in the world we need to keep our players healthy and set a standard that attracts the top international players. We take this responsibility very seriously and in crafting policies regarding player welfare we have reviewed extensive information regarding the adverse health effects caused by the use and abuse of illegal drugs, steroids and related substances.

Second, MLS believes it is critically important for our players to serve as role models worthy of emulation by our fans. With more than 20 million players, soccer is the largest organized participatory sport in this country. Soccer is also the "gateway to a New America" serving as the common denominator for the millions of immigrants who now call our great country home. This convergence of youth and ethnicity that uniquely comes together through soccer provides our League with a tremendous opportunity, and responsibility, to influence positively the behavior of a large and rapidly growing segment of our population. As a League we understand the need to seize this opportunity and have created a policy that we believe sets the highest standards for our players and fans.

Third, soccer is the world's game. MLS competes for its player pool in a world market and, MLS, to a degree, is judged by the success of the United States on the world stage. The United States National Soccer Team that competes at the World Cup and Olympics is comprised of a majority of MLS players. These U.S. National Team players, as well as international players that play for their respective countries' national teams, are often called to compete in international competitions administered by FIFA. As such, MLS determined that it is logical to align itself with the doping policies of FIFA.

Finally, MLS believes that the use of performance enhancing substances compromises the integrity of professional sports. Athletes desire, and wholeheartedly deserve, a "level playing field" where they can compete with integrity to be the very best. There is simply no room for cheaters in sports and as our young League begins to establish its history we refuse to face a future where the performance of our players or the integrity of the world's most popular sport is tarnished in any way.

3. Implementation of MLS' Policy

Major League Soccer's mission is to become one of the world's best soccer leagues and one of America's premier sports and entertainment properties. One such area in which we believe we have taken a leadership role is the development of a comprehensive and forward-thinking Substance Abuse and Behavioral Health Program (the "Program").

Our Program has a four-pronged approach: (i) education, (ii) prevention, (iii) assessment, and (iv) intervention. The Program is administered by Assessment Intervention Resources, a third party which specializes in the education and treatment of professional athletes and entertainers.

The most important part of the Program is the educational component. Each pre-season, and at times throughout the season, MLS players are required to attend a players-only meeting with Assessment Intervention Resources. These meetings broach a wide array of topics. Past meetings have included education regarding the perils of drinking and driving, the use of club drugs, and the importance of safe sex. This pre-season, as a direct response to the tragedy involving Baltimore Orioles' pitcher Steve Bechler, MLS' players were educated as to the dangers involving the use of Ephedra-containing supplements. In order to encourage players to ask questions and seek assistance, the dialogue at the meetings is held in confidence.

As previously stated, another major component of the Program consists of random drug testing of the MLS player pool. If a player tests positive for a prohibited substance, MLS, under the direction of its third-party experts, mandates counseling and treatment for the player in addition to any appropriate disciplinary action. Disciplinary action consists of differing degrees of suspension, with or without pay, up to termination of a player's contract. However, the main focus of the Program is to

identify players with a substance abuse problem and to provide them with assistance.

Beyond these basic components, players and their families are encouraged to take advantage of a 24-hour hotline that allows them to seek counseling or referral for any substance abuse or behavioral health issue.

Ultimately we believe the key to our Program is to remain proactive. Our continual goal with the Program is to prevent tragedies, rather than react to them.

Once again, thank you for allowing me to testify before you today. Major League Soccer appreciates the Committees' diligence in investigating this topic.

Mr. STEARNS. I thank the gentleman.

Mr. Mitten. Professor.

TESTIMONY OF MATTHEW J. MITTEN

Mr. MITTEN. Chairman Stearns, Chairman Greenwood, and other distinguished members of this subcommittee, on behalf of the National Collegiate Athletic Association, thank you for inviting me to appear today to inform you of the NCAA's activities as they pertain to the substance Ephedra.

My name is Matt Mitten, Professor of Law and Director of the National Sports Law Institute at Marquette University Law School, and chair of the NCAA's committee on competitive safeguards and medical aspects of sports.

This committee provides expertise and guidance to the NCAA on health and safety issues, reviews of the NCAA drug testing and education programs, and adjudicates positive drug test appeals.

The NCAA is a private association of approximately 1,200 4 year colleges, universities, and athletics conferences, and approximately 360,000 student athletes compete in intercollegiate athletics at these institutions. One of the guiding principles of the NCAA is in the area of student health and welfare.

The NCAA sports medicine handbook states that it is the responsibility of each member institution to provide a safe environment for each of its participating student athletes and to protect their health and safety.

NCAA member schools take this responsibility seriously, and the NCAA commits significant human and financial resources to ensure the protection of their athletes' health and safety is of paramount concern.

In addition to its committee on competitive safeguards and medical aspects of sports, and these resources include the NCAA sports medicine handbook, which provides sports medicine guidelines for member schools, including the NCAA's recommendations for educating athletes about dietary supplements.

The NCAA's national office employs full-time health and safety specialists who oversee its health and safety initiatives. The NCAA provides two national drug testing programs; random testing under the NCAA's championship competition, and out of season testing, designed to detour the use of NCAA banned drugs, as well as educational seminars to assist universities in developing student athlete drug and supplement prevention programs.

The NCAA conducts national survey research on the drug and supplement use and abuse habits of college athletes. The NCAA's 2001 national drug use survey provides important data on college athletes' use of Ephedra.

Approximately 3.5 percent of its student athletes currently use it, with most beginning to use Ephedrine in high school. The highest use in men's sports is in lacrosse, 5.5 percent, and the highest use in women's sports is in gymnastics, 8.3 percent.

And 24 percent stated that they use Ephedrine to improve performance, and 22 percent as an appetite suppressant; 22 percent for health reasons, and 20 percent to improve appearance.

And based on these survey findings and motivated by a strong desire to protect athletes' health and safety, the NCAA added Ephedrine testing to its year-around drug testing program in August 2002.

This past year the NCAA conduct over 10,000 drug tests for Ephedrine. The NCAA's ban on Ephedrine is part of its overall ban on the use of stimulants. Despite serious health risks, many young athletes may use stimulants to increase artificially or synthetically their energy levels, and to help them lose weight or body fat.

The unregulated use of stimulants, combined with exercise and heat, can cause damaging health effects and even sudden death. All NCAA colleges have agreed through formal legislation not to distribute supplements to athletes unless the products fall into specific defined categories, such as fluid replacement drinks, or vitamins and minerals.

NCAA rules prohibit member institutions from providing Ephedra to student athletes under any circumstances. Ephedra can be found in a multitude of sports supplements that are commercially marketed and available over the counter.

Everything from energy bars to power drinks, to supplement pills and capsules, all of which are legally obtainable, contain ephedra, ephedrine, or ma huang. Product manufacturers target young active people with ads that tout the performance enhancing benefits of cutting fat and increasing energy.

Such ads refer to ephedrine as a natural way to achieve superior performance. The NCAA's significant efforts to prevent its student-athletes from using Ephedra are more fully described in our written submission. The NCAA remains committed to reducing the demand side of the dietary supplement problem in sports.

Its testing, education, and prevention programs are based on national research and administered at the highest level with the strongest possible oversight. Yet it is fair to say that those of us who try to educate and protect young people on the dangers of supplement use often feel like the proverbial long voice in the wilderness.

Thus the NCAA has a strong desire to be a willing partner in any national effort that will enhance the health and safety of its student athletes. On behalf of the National Collegiate Athletic Association, thank you.

[The prepared statement of Matthew J. Mitten follows:]

PREPARED STATEMENT OF MATTHEW J. MITTEN, CHAIR, NCAA COMMITTEE ON
COMPETITIVE SAFEGUARDS AND MEDICAL ASPECTS OF SPORTS

Chairman Stearns, Chairman Greenwood and other distinguished members of the Subcommittee, on behalf of the National Collegiate Athletic Association, thank you for inviting the NCAA to appear today to inform you of the Association's activities as they pertain to the substance "ephedra."

I am Matt Mitten, Director of the National Sports Law Institute at Marquette Law School, and Chair of the NCAA Committee on Competitive Safeguards and Medical Aspects of Sports, the NCAA committee that provides expertise and guidance to the NCAA on health and safety issues, and that reviews the NCAA drug-testing and education programs and adjudicates positive drug-test appeals.

The NCAA is a private association of approximately 1,200 four-year colleges, universities and athletics conferences. Approximately 360,000 student-athletes compete in intercollegiate athletics at these institutions.

One of the guiding principles of the NCAA is in the area of athlete health and welfare. The NCAA's Sports Medicine handbook states that it is the responsibility of each member institution to protect the health and safety and provide a safe environment for each of its participating student-athletes.

NCAA schools take this responsibility seriously and the NCAA commits significant resources to its schools to ensure that protection of athletes' health and safety is of paramount concern. These resources include:

- The NCAA Committee on Competitive Safeguards and Medical Aspects of Sports. This committee is a full standing committee of the Association. Its primary purpose is to advise the NCAA and its members on matters regarding health and safety.
- The NCAA Sports Medicine Handbook. A set of sports medicine guidelines for member schools that includes the NCAA's recommendations on educating athletes about dietary supplements.
- Health and safety specialists. The NCAA national office employs staff members who oversee the NCAA's health and safety initiatives.
- Two national drug-testing programs designed to deter the use of NCAA banned drugs.
- Educational seminars on developing student-athlete drug and supplement prevention programs within the university.
- National survey research on the drug and supplement use and abuse habits of college athletes.

These are a just a few of the many ways that the NCAA commits its human and financial resources to helping student-athletes maintain or enhance their health.

Since 1985, the NCAA has conducted a national study of the drug and supplement use habits of college athletes. The study is replicated every four years and four replications have been conducted since the original study. The study is designed to obtain data on the substances and use patterns of college athletes through the use of anonymous self-report questionnaires. Over 21,000 student-athletes completed the survey in the 2001 study. Copies of the study are available on the NCAA's website at www.ncaa.org.

Prior to the 1997 replication, the NCAA competitive safeguards committee had been monitoring reports of the growing use of dietary supplements, including ephedrine, by college athletes. Accordingly, the committee included questions about the use of supplements on the 1997 survey. The 1997 study found the following regarding college athletes' use of ephedrine:

- 3.5% of the athletes surveyed reported using ephedrine within the previous 12 months.
- The highest rate of ephedrine use among male athletes was in wrestling (10.4%); the highest for women was in soccer (3.3%).
- 50.8% of users said they used ephedrine primarily to improve athletic performance.
- Athletes used ephedrine more in the competitive season, started their use in high school and many used it immediately before or during practice or competition.

Although the study showed that a small percentage of athletes were using ephedrine, the NCAA was concerned that its use was being linked so closely with the desire to improve athletic performance. For this reason, in July 1997, the competitive safeguards committee recommended that ephedrine be included on the list of banned drugs by the NCAA. The NCAA membership agreed with this recommendation and ephedrine remains on the list today.

The NCAA sponsors two national drug-testing programs for college athletes, one during NCAA championships and the other year round. As part of its drug-prevention efforts, the NCAA publishes a list of banned drug classes and tests athletes periodically. The NCAA list, like most banned-drug lists of national and international sports organizations, includes stimulants. Ephedrine is included on that list.

The NCAA drug-testing programs are designed to deter the use of banned drugs. The NCAA believes testing is necessary to protect the athletes' health and safety and to ensure that athletes are not using performance-enhancing drugs to gain a competitive advantage.

The NCAA instituted drug testing at its championships and post-season football bowl games in 1986. Since 1986, any NCAA athlete competing in these events is subject to NCAA drug testing under a strict, published protocol utilizing the best laboratory in the U.S. for sports drug testing that is IOC accredited. Approximately 1,500 athletes are tested each year. Athletes who test positive lose their eligibility to compete in all NCAA sponsored sports for at least one year. Since the 1997 ban on ephedrine, all athletes selected for NCAA drug testing have been tested for ephedrine use.

Primarily to deter the use of performance enhancing drugs such as anabolic steroids, the NCAA implemented a second drug-testing program in August 1990. Today as part of this program, over 10,000 athletes are randomly tested by the NCAA on their campuses August through June. Testing for ephedrine has been included in this program since August 2002.

The 2001 replication of the NCAA's national drug use survey provided additional data on college athletes' use of ephedrine:

- Ephedrine use continues to be reported at about 3.5% of student-athletes.
- The highest use in men's sports now is in lacrosse (5.5%); and the highest use in women's sports now is in gymnastics (8.3%).
- Most started using ephedrine in high school.
- Users stated that they used ephedrine to improve performance (24%), as an appetite suppressant (22%), for health reasons (22%) and to improve appearance (20%).

Due in large part to the 2001 survey findings and motivated by a strong desire to protect athlete's health and safety, the NCAA added ephedrine testing to its year-round drug-testing program in August 2002. This past year the NCAA conducted over 10,000 drug tests for ephedrine.

It should be noted that the NCAA ban on ephedra is part of an overall ban on the use of stimulants. Athletes may use stimulants to increase artificially or synthetically their energy levels and to help them lose weight or body fat. The unregulated use of stimulants combined with exercise and heat can cause damaging health effects and even sudden death.

The NCAA's prevention efforts as they pertain to ephedra(ine) are significant. They include:

- The Dietary Supplement Resource Exchange Center (REC). All NCAA athletes may use this service funded by the NCAA and housed at Drug Free Sport. The REC provides a toll-free number and Web site for athletes to get reliable information about the effects of supplement use. Inquiries are treated in a confidential manner. The REC has an ongoing relationship whereby any reports of adverse health effects of supplement use are reported to the FDA's Medwatch program.
- Educational information on the Web at www.drugfreesport.com.
- Posters explaining the consequences of supplement use.
- Educational conferences for coaches and administrators on deterring supplement use by athletes.
- A national speakers bureau of experts on drug and supplement use in sport.
- The NCAA also communicates through its biweekly publication, *The NCAA News*, which has featured a number of articles on supplement use. A special advisory memorandum from the NCAA also was sent to its members on June 5, 2001 and in January 2003.

All NCAA colleges have agreed through formal legislation not to distribute supplements to athletes unless the products fall into specific, defined categories such as fluid replacement drinks or vitamins and minerals. NCAA rules prohibit member institutions from providing ephedra to student athletes under any circumstances.

Ephedra(ine) can be found in a multitude of sports supplements that are commercially marketed to NCAA athletes and available over the counter. Everything from "energy bars," to "power drinks" to supplement pills and capsules, all of which are legally obtainable, contain ephedra, ephedrine or ma huang. Product manufacturers target young, active people with ads that tout the performance enhancing benefits of cutting fat and increasing energy. Such ads refer to ephedrine as a "natural way" to achieve superior performance. It is fair to say that those of us who try to educate and protect young people on the dangers of supplement use often feel like the proverbial lone voice in the wilderness of this endeavor.

The NCAA remains committed to reducing the demand-side of the dietary supplement problem in sport. Its testing, education and prevention programs are based on national research, administered at the highest level and with the greatest oversight possible. The NCAA wishes to make known today that it is a willing partner in any national effort that will enhance the health and safety of its athletes.

Thank you.

Mr. STEARNS. I thank the gentleman, and I will start with questions. Let me just review for both my colleagues and for the panel and see if this is what I understand. The NFL, the NCAA, and soccer, the Major League Soccer, have an outright ban. NASCAR does not ban it, but they do test it with 10,000 nanograms per milliliter.

And it is not banned by the NBA, baseball, or the National Hockey League. I think that is sort of an overview. Mr. Manfred, is that correct?

Mr. MANFRED. Major League Baseball does ban Ephedrine in the minor leagues.

Mr. STEARNS. That's what I said, in the minor leagues only. So I will start with the question. If you ban it in the minor leagues, why aren't you banning it in the major leagues?

Mr. MANFRED. I think the answer to that is that at the minor league level, we were free to proceed unilaterally. At the major league level, our drug policy, including our Ephedra policy, is one that must be collectively bargained.

Mr. STEARNS. So that was not possible to bargain?

Mr. MANFRED. We have been unable to date to reach an agreement on an Ephedra ban.

Mr. STEARNS. And has it come up in the bargaining every year?

Mr. MANFRED. It did not come up in the last round of bargaining last summer. Since that agreement, we have had conversations with the Player's Association about expanding the policy to include—

Mr. STEARNS. Especially in light of what has happened?

Mr. MANFRED. That's correct.

Mr. STEARNS. Mr. Helton, you are the only one who has actually put a handle here with the 10,000 nanograms per milliliter. How did you come up with that? Is that a threshold that is high or low? I mean, from a scientific standpoint, could other people use it do you think?

Like, for example, the people who have not banned it, would that be a compromise where they could use it? I mean, I am just asking you, and the first question is, how did you come up with that threshold?

Mr. HELTON. From our scientific advisory established the standard, which I understand is a standard in testing. It wasn't set just for Ephedrine. It was set for all of the substances that we would test for.

Mr. STEARNS. Okay. So, Mr. Mitten, what do you think about that threshold that Mr. Helton is using as perhaps a sports standard?

Mr. MITTEN. Well, we think that a complete ban is certainly appropriate in this case. We are relying upon the best available science that we have, and that suggests that a complete ban would be appropriate, and I think it might be difficult as a practical matter, and our student-athletes would be out there trying to—they are going to take this stuff to get a competitive advantage.

Now, I have been a party to about 60 or 70 drug test appeals, and student-athletes say that if it is available over the counter, they think that it is okay to use. And if they think they are going to get a competitive advantage, they are going to do it.

So if there is any kind of a cutoff or anything set, they are going to try to get as close as they can to doing that, and that's why based upon what our science tells us, we believe that a complete ban is appropriate.

Mr. STEARNS. Were you surprised at the use of Ephedrine was basically unchanged according to our 2001 survey even though it was a banned substance? I think you said that 24 percent used it for performance?

Mr. MITTEN. Well, that is for the ones—that is based on the 2001 survey results of the ones who reported, and it was the 3.5 percent.

Mr. STEARNS. And that was from 1997 to 2001, right?

Mr. MITTEN. That's correct. And then we implemented and made Ephedrine a part of our drug testing program in August 2002. So it is rather early on. It has not been quite yet a year, but we anticipate that testing for it is hopefully going to reduce usage, and that will be reflected in our next survey that we will do.

Mr. STEARNS. I guess this is for any of the witnesses. There is a lot of legal stimulants, and obviously caffeine is one of them. How does caffeine, taking 4 or 5 cups of caffeine, that could enhance performance, and that substance is there performing on an athlete in a way that perhaps Ephedrine could, too.

And in fact Ephedrine and caffeine are used in some of the weight loss medications. So my question is to any of you how do other legal stimulants relate to Ephedra, and should we just put in a test instead of an outright ban so that there might be a threshold just like with caffeine and a person could use it?

Mr. ORZA. I don't mind going first here.

Mr. STEARNS. If it is okay with you.

Mr. ORZA. That is a great question because we gloss over in discussions of this kind the actual meaning of terms when we talk about performance enhancement. A baseball player has a headache, and it is not good to sit in the batter's box, or stand in the batter's box, when facing a 95 mile an hour fastball with a headache, and so you take two aspirin.

Are you enhancing your performance by taking an aspirin? Generally speaking, what we have always thought is that the definition of performance enhancement is taking something that the government says you shouldn't take. That is the basis for the Player's Association position.

So if the government says you can take aspirin, that is not performance enhancement. That is getting you back to where you otherwise could be perfectly okay in the context of government regulation.

But this concept of what constitutes performance enhancement deserves some attention by people who discuss this matter. On the one hand, you have something as simple as taking aspirin, and we can all agree that is not a performance enhancing drug.

On the other hand, you take somebody who is ingesting an animal hormone to get bigger, and faster, and stronger, in a very quick period of time, we will all agree that is a performance enhancing substance.

But there is a whole range of substances in between that. Are clubs that give players the thousands of novocaine shots that they get—

Mr. STEARNS. Novocaine shots?

Mr. ORZA. Yes. Are they engaged in a performance enhancing event when they are giving their player—

Mr. STEARNS. Especially a thousand.

Mr. ORZA. Well, there are a thousand novocaine shots administered to players over the course of—or glucocorticoid steroid shots, the legitimate kind of steroid shots.

Mr. STEARNS. I know, but they are steroids?

Mr. ORZA. They are steroidal. They are not the kinds of anabolic steroids that we are concerned about, but they are in an effort to get a player's performance enhanced. This is something that the committee is well served by focusing on.

Mr. STEARNS. Anyone else would like to make a comment?

Mr. BIRCH. If I could comment briefly. One of the key distinctions between caffeine and some of the other products that have been mentioned is the lack of regulation with respect to these other products.

You really don't know—with respect to caffeine that is contained in general food stuffs, coca-colas, things like that, you know what it is that you are getting, particularly dosage-wise.

With respect to these supplements, and in particular Ephedrine, there is no sense whatsoever that a person can really get to understand what and how much of that product is in that particular substance, and particularly what else might be in there that is not even on the label.

So for us it is certainly a much graver risk of harm that might result from the use of Ephedrine products as they currently exist under our framework, as opposed to something like caffeine or another what we consider to be more benign type of stimulant.

The other point is that we do in fact also have thresholds for all of our stimulants, and in fact for every substance that we have on our ban list, there is a scientifically based threshold that we use to determine whether or not it is a positive test result.

For example, with pseudoephedrine, which is obviously in the Ephedrine family, but has legitimate therapeutic benefit—it is contained in many cold and allergy medications—we have raised the threshold to a level that encompasses general therapeutic use.

So if one is using it in normal therapeutic recommended dosages, you will not get a positive test result under our policy, or if you do, we have protocols in place to determine whether or not you in fact were properly prescribed that particular substance by the team physician or training staff.

Mr. STEARNS. My time has expired. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I think all of you, including the NCAA, have acknowledged that athletes, high profile athletes in sports, have a kind of special responsibility, because your competitors, your athletes, do serve as role models for so many young people in this country.

I happen to represent a district in a State that has been the first in the Nation to ban Ephedra. My Governor, Rod Blagojevich, signed into law a ban on Ephedra, and that is perhaps where we are going with this discussion today.

But in addition to the policies, there are other ways to communicate a message, and I wanted to—I don't want to pick on you,

Mr. Helton, but I wanted to focus a little bit on what I think are kind of dual messages. You said you have set a limit, and that you test—although I would be interested in how often, and how regular you test.

But NASCAR has a relationship with NVE Pharmaceuticals, which owns Stacker-2, and has Ephedra and an Ephedra-free dietary supplement, which sponsors Bill Davis Racing, supporting Scott Weimer and Kenny Wallace in the NASCAR Busch Series, and NASCAR Winston Cup Series, respectively.

NVE is also a co-sponsor of the GNC Live-Well Stacker II 250 in Daytona, Florida. And also NVE sponsors the Stacker II WJ Stinger Splash of Energy Tour 2003, which sets up interactive stations at several NASCAR events, where fans can come and sample Stacker II products that boost their energy. That is a quote, boost their energy.

So while there is an acknowledgement of at least potential danger of Ephedra, on the other hand, there is this close relationship, an advertising opportunity, and an actual use opportunity, for fans to sample this. So I wanted you to comment on how you reconcile those contradictory messages.

Mr. HELTON. Well, first of all, I would step back and explain the uniqueness of NASCAR as it relates to its participants, and the fact that car owners, as well as race tracks, are independent contractors to NASCAR.

NASCAR is the organization that pulls everybody together to put the events on. It is membership based and our rules and regulations are policed through that relationship between NASCAR and a licensed member.

As it relates to the specifics of Stacker II and others that you mentioned, those are relationships with the car owners, and not with NASCAR as a policing body or as a company. That relationship is with the car owners.

Certainly as the issue that we are discussing here today became as compounded as it has, we have had conversations with Bill Davis and other car owners who have those relationships, to try and understand their posture with the sponsorship that they have on their cars.

But in the meantime, we are disassociated from those relationships. Those are third-party relationships, and as we become smarter if you will on the issue at hand, those conversations will take on possibly a different light.

Ms. SCHAKOWSKY. Let me just ask you this. The Splash of Energy Tour 2003, that is also separate from NASCAR?

Mr. HELTON. Yes, and I apologize for not understanding exactly what that is. But if you can relate it to either a race track or—

Ms. SCHAKOWSKY. All I had or read was that it sets up interactive stations at several NASCAR events where fans can come and sample.

Mr. HELTON. Yes, Ma'am, and I think what that relationship is, is between that entity that may be doing that and promoting that with the race track and not with NASCAR. Race tracks are independent contractors, just as car owners are in NASCAR.

Ms. SCHAKOWSKY. But of course you can see that I understand that there are details of these contractual arrangements, but clear-

ly you can see how in the minds of fans and television viewers, et cetera, how that might be confused as being promoted in some way by NASCAR itself. I don't know that ordinary people make those kinds of distinctions in the relationships.

Mr. HELTON. And I don't disagree with you. I do agree that I am explaining to you the business side of it. But the reality or the perception is that it is NASCAR related, I wanted to first explain that it wasn't.

But second as I was stating earlier, our intentions at this point is to become as smart as we can on all these issues and details, and then react accordingly as it becomes necessary. I think others in our industry will as well, including the car owners and the race tracks as they see these issues and they become more evident to them.

Ms. SCHAKOWSKY. Thank you. I am out of time and I appreciate it.

Mr. HELTON. Thank you.

Mr. GREENWOOD. The chair thanks the gentlelady and recognizes himself for purposes of inquiry. I am going to ask some questions of you, Mr. Orza, if I may. In your testimony, you said that the position of the Player's Association has long been that the players should not be prohibited from using any substances that the U.S. Government has effectively determined are not unsafe for consumption by other American consumers.

And you also note as you say in your testimony, and as I am sure you know this interest of how best to regulate Ephedra-based products is not new to this committee. That Congress as a whole, with the FDA, in fact believes the debate actually predates Congressional considerations on the passage of the DSHEA Act in 1994. So you know that we have struggled with this issue for well over 10 years.

Mr. ORZA. Yes.

Mr. GREENWOOD. This committee hopes to move that ball forward, but as you also know, it is a lot more difficult to get a consensus or even a majority among 435 members of the U.S. Congress from all over the country, and 100 Senators.

Those of us who happen to have the opportunity to sit in these hearings and have the schedule that permits us to be here all day long for 2 days in a row become very knowledgeable. But the rest of our colleagues are off doing a thousand other different issues, and it is going to take a long time, even if we can come to a consensus and if the FDA can come to a consensus, it is going to take a long time to legislate this. It always does. Legislating was designed to be a slow process. So what troubles me is that you in the private sector representing the Player's Union, you have the opportunity to act much, much more quickly than that.

And I am a little bit troubled by the tone of your testimony, which is we shouldn't have to give this up unless you guys in the government figure out that it is wrong, as if it is in the interests of the players to be able to continue to use this substance until someone tells them no.

It is from all of the testimony that we have had yesterday, it was clear or it was made clear that this product is of very dubious effi-

cacy. In terms of weight loss, I don't have any confidence that this is any good for anybody for the purpose of losing weight, okay?

It is clearly risky. What is in a particular pill that comes out of a bottle is pretty much anybody's guess, because the guys yesterday who were in charge of manufacturing this stuff couldn't even tell us what was inside the capsules. They couldn't even explain their own labels, and what various components actually were, and how much was in it, and that is a pretty frightening thought.

Later on, the Commissioner of the FDA, Dr. Mark McClellan, is going to testify that Ephedra poses special risks in the context of sports performance, with no identified benefit for athletes.

In light of the FDA's—well, let me just stop there. The FDA is saying it is dangerous and it does not do any good. And yet you, representing the players, seem to be saying don't take this away from us; as opposed to saying we have got to get rid of that stuff. And that is what I don't understand.

You talked about aspirin and novocaine. Steve Bechler was not killed by aspirin, and Steve Bechler was not killed by novocaine. It is pretty apparent to me that Steve Bechler was killed by Ephedra.

And rather than sort of holding out the right to take this stuff, I don't know why you are not rushing in to get rid of it, and to protect your young ball players from it, and to do what some of the other gentleman have said, to level the playing field so that the competitive edge comes out of deserved ability, and strength, and talent, as opposed to getting a buzz from a pill, making other players feel like they have to do it if they are going to keep up with the other guy.

So when you negotiate with the managers, and if they put on the table that we think we ought to get rid of Ephedra, and ban it from the players, would you expect to get something back from the owners in exchange for giving up the right to put your players at risk?

Mr. ORZA. There are a lot of questions in that one question, and if I could try and answer some of them. We do not seek anything in return for it, and it is not a subject that we tradeoff something for getting something in return if we agree to ban Ephedrine. It is a much more complicated subject than that I think.

Let me just address some of the things that you have said, first of all. I gather from at least the tenor of these discussions thus far that it most likely will be an academic question, because there is virtually unanimity on this committee at least that something should be done about Ephedra-based products.

As a sign of the Player's Association's commitment and credibility in this area, and Mr. Manfred will vouch for this, we have agreed that anytime the U.S. Congress adds any substance to Schedules I, II, or III, of the CFR Schedule of Controlled Substances, it automatically becomes a prohibited substance.

So it is my hope at least that in fact this question will become academic. I don't mean to duck it. But let's assume—

Mr. GREENWOOD. But you are ducking it. You are ducking the question. What you are basically saying is that until the Congress decides officially in law, through an act of Congress, and signed by the President of the United States, to make this stuff unavailable to us, we choose to continue to put our players at risk voluntarily

when the manufacturers of the substance, or the product, sat here yesterday and said we don't recommend this for athletic purposes.

Mr. ORZA. As I was about to say, let's assume, however, that I am wrong. That in fact there is not a rapid turnaround by the Congress to make this matter become law very quickly. What is the Player's Association's objection to a voluntary ban?

And for that I will just need only a moment of your time. There are some substantial questions wrapped up in the terminology that we use. When we say we ban substances, what we mean, and everybody at this panel says it, they mean a lot more than just that they ban substances.

They say the following. We will come to you at certain times and demand that you give us your urine so that we can analyze it to find out if you have been doing anything wrong. It is suspicionless. But nonetheless we are going to analyze that urine.

I don't mean to be overly graphic here, but there are substantial questions of privacy wrapped up in that. There are also from the Player's Association—

Mr. GREENWOOD. Do you already do urine samples for other substances?

Mr. ORZA. Only for cause, on the establishment of early cause. There is no random testing, because there is nameless random testing in baseball for steroids as a programmatic response to certain claims about steroid use and it really is done for surveying purposes this year.

But we see substantial issues involved in the urine testing of individuals who are not under suspicion for having done something wrong. We think that is a fundamental change in the rules in our society.

Normally we say to people because we suspect you of doing something, we will investigate, and not prove to us that you are innocent. That is the first point. Second, precisely because this issue has been so well discussed in this Congress over the last 10 years.

Now, the clubs have been the beneficiary of the principle of what is called positive inaction in an other area, and that is an area of their anti-trust exemption. When Congress debates things and comes to a conclusion, we rely upon that conclusion.

If this Congress were to say—and I don't mean to interrupt your colloquy, but if this Congress were to say at the end of what we have witnessed this morning that, no, we still think it should be unregulated, that is making a statement to the American people, and that is that this Congress believes that the claims of the lack of safety in this substance—

Mr. GREENWOOD. Mr. Orza, my colleagues have been more than generous, because I have way exceeded my time. It just strikes me—

Mr. ORZA. I apologize for the length of my answer.

Mr. GREENWOOD. It just strikes me as odd that you guys are still philosophizing about this, while the other sports teams have figured out how to deal with it. The gentleman from Texas, Mr. Green, is recognized.

Mr. GREEN. Thank you, Mr. Chairman, and I would like to follow up your line of questioning. I understand that the Commissioner of

Baseball banned the use of Ephedra for the minor leagues in April of this year; is that correct, Mr. Manfred?

Mr. MANFRED. That is correct.

Mr. GREEN. You don't have a collective bargaining agreement with the minor leagues. I guess it is just with the major league baseball players?

Mr. MANFRED. That's correct. The minor league players are unorganized.

Mr. GREEN. Has it been on the bargaining table with the players association?

Mr. MANFRED. In April, the second piece of the commissioner's directive to us, in addition to banning in the minor leagues, was for us to open conversations with the Player's Association in about adding Ephedra as a banned substance. We have had some conversation with the union about that topic.

Mr. GREEN. Okay. Mr. Orza, I come from a collective bargaining background and so I believe in the right, whether you are a major league baseball player making millions, or somebody in my district making \$9 an hour. And I am glad that it was at least broached on the subject.

But it does seem like with major league football, and major league soccer, amateur athletics—and after yesterday's hearing the Oversight and Investigations Subcommittee heard from the mother who lost a 16 year old—I am going to check in Texas to make sure that our UIL for our high school sports also have some type of regulation on that.

But it does seem like it is something—and particularly when the only death that I know of is a major league baseball player, a Baltimore Oriole—that ought to be considered.

I appreciate in your statement that the Player's Association policy has long been that it prohibited substances that the United States government has effectively determined are not unsafe. I appreciate your trust in the Federal Government.

Mr. ORZA. I worked for it for 12 years.

Mr. GREEN. But that trust is not shared by a lot of our constituents, and I also appreciate the support on this committee for the concern about Ephedra, but I also know that we are just one committee and not the whole House, and particularly not the Senate or the Administration.

And a little background. I was just talking to my colleague from Boston. I grew up in Houston working when I was a kid at our minor league ballpark, the Houston Buffs. And when the Colt .45s came in, I worked there as a 15 year old.

In fact, I skipped school to go to the opening day when they were playing the Yankees because I could sell soda water that day. But the image I guess I have of professional baseball, and football, and soccer—my son is 27 and played soccer from the time that he was 5 years old—is the role model that athletes have, not only for my generation.

And as one of our female colleagues left, she said, "I am going to leave it to the aging jocks to be on this committee here." So I would encourage you as much as you can. One, I hope that you trust the Federal Government, but I wouldn't trust it so far to say that whatever we don't prohibit is good.

I drink a lot of diet coke, and we have not had any deaths from diet coke caffeine. Years ago a doctor told me that if I drink as much as I do, and it is a diuretic, and I will end up losing most of it before it has an impact on me.

But I would encourage the players association and the owners to sit down and deal with it because of the image for our children. And as sure as I am sitting here, there is another 16 year old, or 14 year old, whether it is myself or Eddie Markey from Boston when we were young, who idolized those players, and to see if that is an issue.

And I would just encourage you to not wait on Congress to deal with that problem, particularly because of the death of the Oriole pitcher. And with that, Mr. Chairman, I will be glad to yield back, unless Mr. Orza wants to respond. Again, as a lawyer, I always at least needed to have my response back.

Mr. ORZA. If you have not got a question for me, I don't want to interpose on you. I would simply say a few things. First of all, Rusty Staub is my best friend.

Mr. GREEN. Rusty was—I was 16 years old, and Rusty was playing first base for the Houston Astros or Colt .45s.

Mr. ORZA. I am glad that Mr. Manfred clarified what would have otherwise have been a mistake in the record so to speak about whether or not Ephedra was raised in our collective bargaining discussions prior to the conclusion of our collective bargaining negotiations this past round.

But that is not to criticize the clubs. The reason that they didn't mention the word Ephedra in those negotiations is because that until Mr. Bechler's death, we had not had a player at any time in our history on the disabled list even for the misuse of an Ephedra-based supplement.

That is not to say that it is good. What I am saying is that on the radar screen in terms of those negotiations, it was only Mr. Bechler's death which was called into question. Second, Mr. Bechler's—as a lawyer, I am very, very reluctant to get involved in discussing what I understand is now a case in litigation, and I don't mean to.

But I think everyone agrees that Mr. Bechler's death, in the case of Mr. Bechler's death, his use of the substance was for dietary purposes, and not performance enhancement purposes.

Baseball players are not typically the universe of individuals about whom we must worry about their dietary consumption. They are in pretty good shape to begin with.

I understand the committee's concern, and we share it about baseball players as role models, and what we can do, and I can assure you that we will do all that we can do in this area consistent with our obligations to the players.

But I just say finally that it is counter-intuitive to suggest that anyone in the world cares more about the health of baseball players than all the individuals in my office, who have devoted their professional careers to them.

Don Fehr, 25 years; me, 19 years, Don's brother, 22 years; my associate, Michael Weiner, 18 years. No one, no one cares more about baseball players' health than we do.

Mr. GREEN. And there is no question on that. I would just say that compared to the NFL that not only prohibits the use, but also any commercial sponsorship by an athlete. So I think there is an item there.

Mr. ORZA. We have communicated with players on that very subject. Do not promote. I had a conversation with a player on the Minnesota Twins just the other day about the possibility that he was going to enter into a contract promoting a substance that was Ephedrine-based, and he knew enough to call, and he knew what his answer would be. Do not do it, and he didn't do it.

Mr. GREEN. Mr. Chairman, I have run over time, but I appreciate it.

Mr. STEARNS. I thank the gentleman. The gentleman from New Hampshire, Mr. Bass.

Mr. BASS. Thank you, Mr. Chairman. I think I am going to give Mr. Orza a little break here.

Mr. ORZA. Thank you, sir. I appreciate that.

Mr. BASS. I would like to ask a question of the rest of the panel. Can you tell me any reason why it would not be in the best interests of the individuals whom you represent, the groups that you represent, to make Ephedra a prescription drug?

Mr. MANFRED. We think that is the appropriate treatment for Ephedra. We believe that.

Mr. BIRCH. We are in agreement with that, not only for Ephedra, but a number of other things that fall in that dietary supplement category.

Mr. HELTON. I think our position right now is that we are on a fact finding mission as much as you may be, and that this exercise and the opportunity to be a part of these last 2 days will help us. But right now it would be premature, and we are not qualified to answer the question right now.

Mr. GARBER. On our behalf, it will still be a banned drug as part of our testing program, but it certainly would limit the issues that we would face as it relates to the result of that ban.

Mr. MITTEN. The NCAA would continue its ban, but we have a process where you can obtain a medical waiver for a banned substance. In the case where Ephedra were prescribed for a legitimate therapeutic reason, that would be something that would be considered and approved if appropriate.

But that would eliminate the problem of using it for performance enhancing or instances where it would expose our student athletes' health and safety to risk.

Mr. STEARNS. Will the gentleman yield?

Mr. BASS. Certainly.

Mr. STEARNS. You have a very good point there. Let's say that Congress mandated that it would be a prescription, and then a player got Ephedrine. What would that do in the case, Mr. Helton, where this person is going to race cars and the doctor has prescribed it to him. Then would that mean that your threshold would not apply?

And I guess that is the question that my colleague from New Hampshire had, that if it is prescribed, then what does that mean in terms of those athletic organizations that ban it? Does it then

become available and accepted by these organizations. So I yield back.

Mr. BASS. Would you gentlemen care to answer that?

Mr. HELTON. I think I was directed a question. I am not sure, but in an attempt to answer it, the substance abuse policy addresses-NASCAR's substance abuse policy addresses all substances, including prescribed drugs already.

So if Ephedrine became a prescribed drug, it would still fall under our substance abuse policy as something that we would police and look for.

Mr. BASS. Mr. Chairman, I don't have any further questions.

Mr. STEARNS. Would anyone else like to comment on my question, which is basically then, I guess, that you are saying that in the minor leagues, for example if somebody prescribed Ephedrine and you found it, you would not let that person play, even though the doctor prescribed Ephedrine?

Mr. MANFRED. No. Both the major league policy and the minor league policy prohibit the misuse of prescription drugs. If a player had a prescription validly issued by a physician, and tested positive, we would not treat that test as a positive, because there are a number of substances on the Code of Federal Regulations' schedules that have valid mediastinal purposes.

And if they are given under a doctor's care pursuant to a valid prescription, we would not treat that as a positive test result.

Mr. STEARNS. If I could continue to use the gentleman's time if I may. Then what would happen with valium? Let's say that a doctor prescribed valium for depression, or zoloft, and then you found a lot of this in there. Then you would allow it, even though the rest of the players could not use it.

Mr. MANFRED. It would return as a positive, and then we would make inquiry as to the medical situation, whether there was in fact a prescription, whether he was in fact under a doctor's care, because the way that the policy is written, it does cover misuse of prescription drugs.

In other words, if it is a situation of abuse where the prescription is not valid, and he is not really under a doctor's care, that player would be subject to discipline. However, if it is a legitimate treatment modality, that individual would be allowed to use it.

Mr. BASS. If I could reclaim my time just for a second.

Mr. STEARNS. All right. Reclaiming your time.

Mr. BASS. Are you saying that if I were an athlete and I went to a doctor, and the doctor said that we have got to prescribe amphetamines or something because if we do, you will have more energy, and you will be more alert, and will win more prizes, that you have to let them do it?

Mr. MANFRED. No. That's why the policy prohibits the misuse of prescription drugs. If he turned up positive for amphetamines as you postulate, we would make inquiry as to who the doctor is, why he was—and particularly with an amphetamine. It is an unusual thing to be using that.

Mr. BASS. I use an extreme case, but what if the doctor said, oh, yeah, well, this guy, he has been a little low for the last few months, and we think he can run a quarter-of-a-mile in 5 seconds. But I am a doctor, and I have a valid prescription here.

Mr. MANFRED. No, there would have to be a medical reason for the use of the prescription drug.

Mr. BASS. Mr. Chairman, I don't think that this is really germane to the hearing and so I am going to yield back.

Mr. STEARNS. All right. I thank the gentleman, and Mr. Stupak is recognized for 8 minutes.

Mr. STUPAK. Thank you, Mr. Chairman. Mr. Helton, you have this standard which is 10,000 milligrams per what? What is your standard there?

Mr. HELTON. The standard is that for every substance that is tested, and I referred to it as Ephedrine, but it is 10,000 nanograms per milliliter.

Mr. STUPAK. Nanograms per milliliter.

Mr. HELTON. That's right.

Mr. STUPAK. Okay. How did you establish that standard?

Mr. HELTON. That was established by our scientific advisor in helping to establish our substance abuse policy back in 1998.

Mr. STUPAK. Okay. It goes on to say in your testimony that the policy provides for testing under reasonable suspicion.

Mr. HELTON. That's correct.

Mr. STUPAK. If you are more than 10,000 nanograms does a driver act differently with the substance, or how do you really under reasonable suspicion, what leads to a reasonable suspicion before you would test someone?

Mr. HELTON. The reasonable suspicion approach has from NASCAR's application of its substance abuse policy has no bearing on the 10,000 nanograms per milliliter. I used that as a reference of what the standard is in our policy, and that we feel is the standard in athletic testing based on our scientific advisors.

Mr. STUPAK. Well, how would you test someone? I mean, have you ever tested anyone for Ephedrine?

Mr. HELTON. Well, when we test someone, we test for a variety of substances, and Ephedrine is one of the substances that is tested for.

Mr. STUPAK. But there is no circumstances under which you would just test for Ephedrine? You have a standard on alcohol that is .02 isn't it?

Mr. HELTON. Well, again, the standard is in the substance abuse testing that the lab does, and I am not sure exactly what that is, and what it would register on our test policy. But as we become smarter about Ephedrine, it may be that it has its own characteristics that would signal to an official that there is reasonable cause to test.

Mr. STUPAK. Well, I guess that is what I am trying to get at. Is there any characteristics or unique circumstances that would lead you to cause to test for Ephedrine?

Mr. HELTON. I think that as we get smarter that there may be, but in the meantime it comes as a result of an action that is unlikely or different, as it would be for other substances that might be causing a problem.

The attitude, the actions, the dizziness, the red eyes, the different characteristics that you would look for, or that would give you reasonable suspicion in the event of or during the event that an official would recognize.

Mr. STUPAK. Well, let's take alcohol. It is my understanding that the limit that NASCAR has set for race day is 0.02 blood alcohol content. Does NASCAR administer breathalizers on competitors on race day?

Mr. HELTON. No, we do it through our substance abuse testing, which is the urine sample.

Mr. STUPAK. Okay. Do drivers get that every race then?

Mr. HELTON. No, it is again reasonable suspicion. IT is not a random or routine test.

Mr. STUPAK. Okay. So you would almost have to see like someone having alcohol on race day or something and before the race in order to do this?

Mr. HELTON. We would have to have suspicion, and sometimes it comes from information from someone that has been around an individual, and certainly observation is one way.

Mr. STUPAK. Okay. So the only way to monitor this, at least in NASCAR, is if someone would say something. I am trying to find out how you monitor for this if you don't give urine tests the day of the race, and you have this 10,000 standard that leads me to these questions.

How do you ever determine whether a competitor has consumed an improper dosage of Ephedrine or anything else? I mean, it would be through a urine test, right? And you would have to have some other reasons, like alcohol or something, to have someone take a urine test, and not just based on Ephedrine?

Mr. HELTON. It would not lead us to reasonable suspicion just based on alcohol consumption. I go back to my opening statement where I was trying to explain the uniqueness of NASCAR in relationship with its officials and its competitors, and the fact that we will have over 75 officials at the beginning of the event that is within an arm's length basically of the competitors through the entire 3-day weekend.

That relationship, along with the high level of interest of competitors who are working with other competitors to police each other, gives NASCAR a unique ability to identify something that may have changed, or a situation that may have occurred that gives us reasonable cause to look at it.

Mr. STUPAK. There is an article in U.S. Today by an Alan Shuford, if I am saying that right, but an Alan Shuford of U.S. Today, who quotes that 80 percent of NASCAR crew members have tried Ephedra. What is your thoughts on that claim?

Mr. HELTON. If I recall the article correctly, he was quoted as saying that as a team representative of Ganassi Racing, which operates three teams in a garage area, that he understood that 80 percent had tried it.

As we followed up on that comment, we found that maybe that was not quite accurate from his opinion, but also I would point out the fact that if 80 percent had tried it, we don't feel like today that there is a misuse, or maybe the current level of usage.

Mr. STUPAK. So you did some investigation into it other than—

Mr. HELTON. We did have a conversation with Alan Shuford and the team members on that team to see if that was an accurate statement on his part.

Mr. STUPAK. Okay. Any others? Soccer, I think you banned it, and NCAA, I think you banned it. Minor league sports. Do you have a standard like 10,000 nanograms per milliliter or anything like that? Just an outright ban on Ephedra?

Mr. MITTEN. The NCAA has an outright ban.

Mr. STUPAK. Is that the same with soccer?

Mr. GARBER. Yes, there is a standard, but I am not sure of the specific measure, but it is an outright ban.

Mr. STUPAK. If you have a measure, how would you measure it then? What do you look for that would tip you off that a soccer player might have been using it?

Mr. GARBER. It is done by our testing service, and I don't have the specific measure through.

Mr. STEARNS. Do you do random testing of players then?

Mr. GARBER. Yes, of all of our players.

Mr. STEARNS. Okay. How about minor league baseball?

Mr. MANFRED. We have a complete ban on Ephedra use, but with respect to all banned substances and all testing programs, there are scientific trigger levels below which they cannot be certain that the particular substance has been ingested. I believe that our Ephedrine level is a thousand nanograms, the one we use in the minor league program. I would have to check that to be certain for you.

Mr. STUPAK. Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. STEARNS. I thank the gentleman. I wonder if I could follow up a question using your time?

Mr. STUPAK. Sure.

Mr. STEARNS. So you use 10,000 nanograms per milliliter, and you use a thousand nanograms per milliliter.

Mr. MANFRED. I believe ours is a thousand.

Mr. STEARNS. So why yours versus his? Why don't you use his?

Mr. MANFRED. I think or I know that the way that our standard was developed was examining drug testing policies used in other contexts. For example, the Olympics has a very well published—

Mr. STEARNS. Is the Olympics a thousand nanograms?

Mr. MANFRED. I can't tell you what the Olympics is off the top of my head.

Mr. STEARNS. Does anyone know what the Olympics is? No? Okay. Mr. Birch.

Mr. BIRCH. I believe the Olympics is 10,000.

Mr. STEARNS. 10,000, like NASCAR.

Mr. BIRCH. But part of the issues with that is that a lot of it depends on when you test in relation to use as well. So you have to guide your testing pattern based on whether you are testing players within 10 hours of suspected use, and then that might require a different number than if you are testing someone within 2 days of suspected use.

Because at that 2 day point, a vast majority of it is going to be gone, and so you would need to go to a much lower level to detect. So all those things I think it is fair to say from Rob's perspective are really somewhat dependent upon the sport and your testing policy.

Mr. STUPAK. Okay. Mr. Helton.

Mr. HELTON. If I could clarify. The 10,000 nanograms per milliliter is unique to Ephedra. The other substances can vary. It could be lower than 10,000 on other substances, but 10,000 is the standard that was established in our policy, and I think based on the fact that it was a standard in athletic testing.

But it is unique to Ephedra. Other substances could have a different level that we test for.

Mr. STEARNS. I understand. The gentleman's time has expired. And I thank him for his courtesy. And the gentleman from Oregon, Mr. Walden.

Mr. WALDEN. Thank you very much, Mr. Chairman. I appreciate the opportunity to join you again today for day two of these hearings. Mr. Orza, I am trying to figure out what all your contracts do in terms of restricting what players can ingest. Do they have anything or say anything about consumption of alcohol prior to a game? Is there any prohibition on players having a few beers before they go out?

Mr. ORZA. Well, the collective bargaining agreement embraces a uniform players contract, which all ball players are signatory, and they must maintain themselves in playing condition.

So if a player had a few beers and was unable to play by virtue of that fact, he would be subject to discipline, or even to being taken out of the game.

Mr. WALDEN. What about smoking? Do you restrict players who smoke? Is that allowed? Can you be a baseball player and smoke?

Mr. ORZA. Well, of course you can smoke, and you can drink beer after a game.

Mr. WALDEN. How about prior to a game?

Mr. ORZA. Well, they are not tested for whether they have had beer at lunch when they play a night game. I mean, there is beer in the locker rooms at the end of the games.

Mr. WALDEN. But what if the coach came in and they are all sitting around having a couple of cigarettes and some beer before they go out to throw a few around the field with their buddies?

Mr. ORZA. Well, it is not in their best interests to do that in terms of the length of their career. I think the coach might get a little bit upset about that.

Mr. WALDEN. Okay. So I guess what I am leading up to obviously is that those are not banned substances by the Congress are they? And yet baseball has said it is probably not a good practice to do that.

Mr. ORZA. And we say it is not a good practice to take any Ephedrine-based substances. We do that in meetings, mass meetings, communications, jointly authored pamphlets. We have gone through to great lengths to try to educate players about the evils of not only Ephedrine-based products, but indeed alcohol, which has taken more lives of players than any other substance, and cigarettes.

Mr. WALDEN. What about—I understand you also have a clause that prevents players from engaging in hobbies and recreational activities that may pose a risk to health, correct?

Mr. ORZA. Well, it depends on what you mean by that.

Mr. WALDEN. Well, sky diving, auto racing.

Mr. ORZA. We have clauses in our guarantees that exempt the club from being obligated to honor the guarantee if the loss of the player's services are occasioned by engaging in those kinds of things. He does not lose his contract. What he loses is the protection of the guarantee.

Mr. WALDEN. Does it violate the term of the pivot activities clause?

Mr. ORZA. I'm sorry? The what activities?

Mr. WALDEN. My understanding is that if a player violates the terms of the pivot activities clause that the contract may be voided.

Mr. ORZA. I'm sorry, but I don't know what pivot activity means.

Mr. WALDEN. We are talking about clauses which prohibit activities which are dangerous.

Mr. ORZA. Well, I'm sorry, but I just did not understand the word pivoted.

Mr. WALDEN. Well, prohibited activities.

Mr. ORZA. Well, there is a provision in the uniform players contract which tells a player that if you engage in these activities and you sustain an injury, the club's obligation to pay you is limited under certain circumstances set out in the contract.

Mr. WALDEN. Okay. Given that the FDA Commissioner's statement today that Ephedra poses little or no benefit for athletes, is it now medically irresponsible for baseball teams to allow its players to use Ephedra?

Mr. ORZA. Well, I don't believe that major league baseball teams, as you say, continue to allow. I believe they have been taken out of locker rooms and everyone in baseball is telling them that there really is no reason to take them. They should not take them.

Mr. WALDEN. Then what is wrong with negotiating an agreement to ban it?

Mr. ORZA. Because the ban is accompanied by an imposition on their liberty to disagree with us as adults. It is accompanied by their urine testing to determine whether or not they are honoring our view of the world. There are a variety of reasons not to have it.

Mr. WALDEN. Does it happen in other professional sports teams that have already gone down this road?

Mr. ORZA. Yes, they have.

Mr. WALDEN. And has there been some sort of strike action as a result of that? Does anyone want to speak to that on the panel? I mean, how have the other teams that have banned this responded? I mean, is it that big of a deal?

Mr. BIRCH. Well, from our end, fortunately this is one of the areas that our players association was pretty much on the same page with us. They are very concerned about the health and safety of their players, and when presented with information that suggests that a product is either dangerous and/or provides a competitive advantage, we actually were able to wrap this part of the process up in a remarkably short amount of time.

I think that there certainly are issues that have to be addressed and it may take some time to work out, but we were able to do it in our case.

Mr. WALDEN. I appreciate that. I guess what has caused me to become so involved and so trouble by this whole issue of Ephedra

is that it appears to me that the way the Federal law works today, somebody really has to get injured and suffer miserably, and then the FDA has to come in and prove that that was a direct result of Ephedra.

And yet I think that most of us agree when you look at the incident reports, when you look at the scientific data, that something can go horribly wrong in many people's lives when they take servings—it's funny, I have never taken a serving out of a capsule before, and don't intend to now.

But when you take this stuff, and I don't know a lot about professional sports, and I admit it, but I have been in greenhouses, because I have some in my district, and if you never allow a greenhouse to vent, everything inside dies. That is the effect of what scientists tell us of what can happen if you exercise and take these servings.

It's that your body never is allowed to vent because of the thermogenic reaction. It just heats up and you don't sweat, and you die, or you suffer some other problem. And I believe that is what happened to Steve Bechler, whose parents live in my district.

And I believe that is what happened to Mr. Riggins' son, and we ought to do something about it. But in the meantime, my greatest fear is that there are going to be a lot of innocent people out there who buy into the claims that are exaggerated and hyped, and who believe that they can be a little better athlete and maybe make the team if they just took some of this stuff, and maybe one extra won't hurt them, and they end up outside down. I have used up my time. I think you, Mr. Chairman, for your indulgence.

Mr. STEARNS. From Missouri, Ms. McCarthy is recognized for 5 minutes.

Ms. MCCARTHY. Thank you, Mr. Chairman. I want to thank the panelists for being with us today. And I represent an area in Kansas City that proudly includes the Royals, and the Chiefs, and right across the State line, NASCAR.

And I know what a boon that is to our economy and to our community spirit, and so I just want to begin by thanking you for all that you do to enhance that. I have listened carefully today and I apologize for missing yesterday, as I had a Hellman and Security Meeting that I had a conflict with.

And I have two teenage nephews and they love sports and often go with me to Royals games, and Chiefs games, and NASCAR races. And I used to be a high school english teacher, and I am thinking about the message to our children. I appreciate all that professional sports is trying to do with regard to this particular issue.

But sports figures are heros or heroines to young people growing up, and I see that not just in my nephews, but all over. And they send messages that are cultural and otherwise by their actions and behaviors.

And basically by allowing any use at all of this particular drug, one of the messages that is being sent is risk your health for fame. And it is not unique to sports. The music industry and other celebrities send a similar message when they abuse substances.

But I would like to think that in the sports world where the players, the performers, the drivers, are heros to our young people. And

that they would—that they and their owners would not be looking at the bottom line as much as they would be at America's future, and that those sports figures would forego activities that if their fans thought were okay, because of course this is what makes them a great player, or a great driver.

This is what I should do, too, and it would stop that kind of message. It is very troubling to me to see young people today who are anorexic because dieting is so important, and weight is so important. I think about in my youth that sports figures, while they may have had troubles, they were perhaps like drinking too much beer.

But not altering their body state to be something that they aren't naturally, and so I guess I just wanted any thoughts that you had on how we in America could go back to the idols of the sports world in such a way that it really is a positive role model for our young people coming along as they aspire to similar greatness without taking artificial means to get there.

To me it is a very troubling message. If you can't just be what you are, and you look to substances that are dangerous to change so that you can be something that you want to be, that is not the American dream I grew up with.

So I would really love any of you to reflect on that, and how in your organizations if you are at all thinking about that, and what steps you might be taking to do that for the young people and for the future of sports. Thanks.

Mr. GARBNER. I will give it a start and I will politely point out that the Kansas City Wizards play in Arrowhead, a major league soccer team. It starts with education. It starts with having the time to spend with your athletes to have them recognize the role that they play in our society.

Much of that extends then to contractual obligations. Many of our teams, and the Kansas City Wizards, as the Chiefs, are owned by Lamar Hunt, and have a contract with their athletes that require them to make public appearances and to have clinics with young players, and to go out and spend time with young people.

As it relates to drug abuse, it is having very strict testing programs. I will point out to the chairman that in major league soccer that we have even banned the abuse of caffeine, and caffeine is tested as part of our drug testing program.

It is our view that our athletes need to perform on a level and should not use stimulants to enhance their abilities. And we are very strict about that, and we have the benefit to not have a collective bargaining agreement. Our players are not unionized, and we are going through that process now, and we are confident that we will be able to maintain the strict testing program that we have.

When our program was started, we had the ability to take a step back and learn from the other leagues, and come up with a program that we felt would enhance the role that our players have in their community, and to be clean and to be drug free, and to not use and/or abuse stimulants, is one way to do that.

I am sure that my colleagues in other sports have many other things to add to that.

Mr. MANFRED. In my initial remarks, I talked a little bit about this whole role model phenomenon as one of the concerns that drove us to develop new policies with respect to the players' side,

but it has also carried over into the business side of major league baseball.

We have a prohibition on any club having a sponsorship arrangement with a manufacturer who makes nutritional supplements that are on our banned list; the precursors, the Ephedrins, and we did that because based on a lot of the concerns that you articulated.

I think the only thing I would add in that regard is that in enforcing this sponsorship ban, because of the lack of regulation in the area of nutritional supplements, like a Federal regulation, it is a major chore just to figure out what companies are making what products, and what those products contain in order to enforce this sponsorship ban.

And again I think it makes the point that this entire supplement area cries out for a new fresh look as to whether we are regulating it appropriately.

Mr. MITTEN. I think you raise an excellent point on that. At the NCAA level, what we do is we directly educate our student athletes, but one of the problems is at the high school level.

There is the pressure to get a scholarship, or if they want to be a professional athlete, and I have heard on drug test appeals that a student admits to using it at the high school level. They want to get that education. They show up for football practice or whatever and they hear about it, but the damage has already been done in a lot of instances.

So that's why I think it is particularly important to have some regulation of this.

Ms. MCCARTHY. Mr. Chairman, I realize that my time has expired, and could I ask for unanimous consent if there is anyone else wishing to comment?

Mr. STEARNS. Does anyone else wish to answer her question?

Mr. HELTON. I would simply say that I think all of us agree with your sentiment about role models and the fact that all of our sports depend on the character and the characteristics of its athletes to be role models, because that is what attracts all ages to the sport.

And I think we all take that very seriously beyond just this substance abuse. I think the actions on the field, or on the race tracks, our reactions to those actions I think all of us have a great concern to be very conscious and sincere about the role models that are athletes are.

Mr. BIRCH. And I guess briefly I would add that from the NFL's perspective we do feel strongly about that point, and we do think that frankly a large part of the driver for change in the industry came as a result of some of the actions that we took, in terms of banning and making it know that we were banning that substance when we did.

It is hard to obviously gauge what amount of that might have been as a result, but certainly it was pointed to as one of the bases for that type of decision when ultimately it might have become unprofitable for that company or those companies to continue manufacturing those products.

Ms. MCCARTHY. Thank you very much, Mr. Chairman.

Mr. STEARNS. The gentlelady's time has expired. The gentleman from Massachusetts, Mr. Markey.

Mr. MARKEY. Thank you, Mr. Chairman. Mr. Orza, you have the responsibility to protect the health of the players. Yet you say you won't take preventive measures as long as Congress has not banned it.

Well, Congress has a lot of responsibility; to the public health, to the economy, to the jobs of our constituents. And while I believe that the Congress should ban this substance, it will not surprise me if we never do it, because there are lots of important matters before Congress that we just never seem to reach.

Meanwhile, you, who have only the health of the players to look after, are abdicating your responsibility to those whose focus is less exclusive on the players, the people sitting on this panel. And you are saying when we get around to it, then you will accept the ban, and of course you will accept the ban because it will be the law of the Nation.

You don't abdicate, Mr. Orza, other aspects of baseball to this committee, and you don't wait for us to ban the corking of bats, and you don't wait for us to make decisions with regard to eligibility of players, or how long the contracts are.

But on this one subject, you say that we are going to leave it to the Congress, the health of the players. Well, it seems to me that you are leaving the most important issue to us, and I don't think that is a good idea, Mr. Orza.

In other words, I don't think it is a good idea for the owners to say that in the farm system where they have authority that these kids can't take these dangerous substances, and they go through A and AA, and AAA ball, but as soon as they leave the farm system, and go up to the majors, they go from the farm system to the pharmacies so they can now compete with all the players that you are representing.

Because these kids have no choice now. They have kind of left the controls of the owners almost playing the role of parents for these young men, and saying you should not put these substances into your body.

And then you say, well, we are going to leave it to these young men now who are 22, 23, 24, 27, 28, and they are going to make up their own minds if they want to put this stuff into their bodies, even though the NFL, and Major League Soccer, and others have all come to a conclusion based upon obvious evidence that it is dangerous for these young men.

So, Mr. Orza, when is it your responsibility to make these decisions, and when is it that you say that we can't wait for Congress anymore because you might be waiting for another 20 years for this Congress to actually ban this substance.

Mr. ORZA. Despite the numerous areas in the past that we have agreed on, I am afraid that we are going to have to disagree respectfully with you on this one, Congressman Markey. As I said earlier, and I think you were out of the room at the time, it is intrinsically counter-intuitive to suggest that somehow people who work at the Player's Association do not care as much as someone else about the health of their members.

Our job is to protect their interests, and their interests are much broader than only their health. They include also their liberty, their rights, and these are—the Congress made a conscious deci-

sion several years ago, and we did not support that decision necessarily, but the Congress made a conscious decision to say the following universe will be composed of food.

And you made certain substances food, and now because you are in a debate with other Members of the Congress about whether or not they should continue to be the functional equivalent of food or should be banned as drugs, you want to say that we may not be able to change that point of view, but indeed we would like you to do the following, Mr. Orza, or Mr. Fehr, on behalf of your members.

We would like you to agree to include this substance on the list of banned substances because it is bad for your members. Is beer next? Is beer a prohibited substance under our agreement? Because in fact more ball players have died from beer consumption than from the consumption of Ephedrine.

Tobacco. There are numbers of people who are receiving survivor benefits under our pension program because their husbands smoked.

Mr. MARKEY. My time is going to run out. Let me go to you, Mr. Manfred, okay? So the issue is in this negotiation, just so I can understand it, is that you want to ban it. So there is a kind of bad for baseball clause, or a kind of a doctrine of bad for baseball, and corked bats fall under that category.

But I guess I would put this under bad for players, although it is also bad for baseball that some players want to juice themselves up so that the young kids coming out of the minors who are clean now have to take it to compete with the players who are taking these drugs.

So do the interests of these players, these young kids, to make more money and as a result have to put these bad things in their bodies, does that trump their health, Mr. Manfred, and how do you weigh it at the owners association?

Mr. MANFRED. Well, I think that we have had a tremendous concern going back a number of years that there was an incentive in part because of the economics that surround professional sports for players to use substances that could be harmful to them in an effort to make it to the major leagues.

That's why major league baseball undertook its testing program at the minor league level. We believed that whatever agreement we could or could not make at the major league level, that it was incumbent upon us to devote major league baseball's resources to a strict testing program in the minor leagues because of the youth of those players, because of the health issues associated with the use of some of these substances, and on the theory that if they couldn't use it in the minor leagues, they would be less likely to feel that they needed to use it at the major league level.

Mr. MARKEY. Well, I hope that the NFL's example, and Major League Soccer's, is followed in Major League Baseball, and I congratulate the owners. I hope that you continue to press, because I think the long term well-being of these young men is at stake.

We will come back in 40 or 50 years, and we will have old men complaining about the impact on their body that is a direct result of taking stuff as young men that they felt that they had to take because it was legal within a profession, but they had done quite well without it until after they had left the minor leagues.

Mr. MANFRED. Well, I appreciate your sentiment and I can tell you that Commissioner Selig will not allow us to do anything other than continue to press on this issue. Thank you.

Mr. MARKEY. Thank you.

Mr. STEARNS. The gentleman's time has expired, and I think we have finished with the first panel, and I want to thank them. You are excused, and we bring up the second panel.

[Brief recess.]

Mr. GREENWOOD. The meeting will come to order. Welcome Commissioner McClellan, and welcome Director Beales. We thank you for being here. Let me officially introduce the Honorable Mark McClellan, M.D., Ph.D., as the Commissioner of the Food and Drug Administration; and Mr. J. Howard Beales, III, as the Director of the Bureau of Consumer Protection, Federal Trade Commission. We thank you both for being here.

We apologize in advance for the pounding that you hear upstairs. It is some sort of progress no doubt, and will probably continue until just about when the hearing is finished.

You gentlemen both are aware that when the oversight investigations subcommittee holds hearings that we take testimony under oath, and so I need to ask if either of you object to giving your testimony under oath. I am sure that you do not.

I also need to inform you that pursuant to our rules, you are entitled to be represented by counsel. Do either of you request to be represented by counsel? I assume not. Then if you would stand and raise your right hands.

[Witnesses sworn.]

Mr. GREENWOOD. You are both under oath, and we will begin with Commissioner McClellan. You are recognized and again, welcome, and thank you for joining us, and you have 10 minutes for your opening statement.

TESTIMONY OF HON. MARK B. McCLELLAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND J. HOWARD BEALES III, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. McCLELLAN. Thank you, Mr. Chairman. It is a real pleasure to appear before your subcommittees about the FDA's recent actions related to dietary supplements containing ephedra or ephedrine alkaloids.

I am going to be talking about ephedra in particular, but I mean this whole class of substances. I am pleased to be here with my colleague, Howard Beales, from the FTC, with whom we have worked increasingly close to enforce the law against dietary supplement manufacturers who make misleading claims about their products.

I have been at the FDA for about 8 months, and there are many urgent public health priorities that the agency needs to work effectively and creatively to address. Among my top priorities have been taking effective regulatory action on dietary supplements containing ephedra and increasing enforcement actions against dietary supplements making bogus claims about their benefits or risks that are not based on sound science.

As part of this process, we are now in the midst of an ongoing review of ephedra, and we have also taken significant new steps to

restrict the marketing and sales of ephedra. We must take all these actions under the unique authorities given to the FDA to regulate dietary supplements as part of the DSHEA legislation of 1994.

Under the Dietary Supplement, Health, and Education Act, DSHEA, Congress defined the term dietary supplement as a product that among other things is ingested, is intended to supplement the diet, is labeled as a dietary supplement, is not represented as a conventional food, or is the sole item of a meal or a diet, or contains a dietary ingredient.

This is a large and diverse set of products that includes vitamins, minerals, amino acids, enzymes, and herbs, and botanicals, as well as their metabolites, concentrates, and extracts.

Dietary supplements are found in many forms, such as tablets, capsules, liquids, bars, and they are used by most Americans. Most dietary supplements don't raise significant safety concerns and in certain cases they have even been demonstrated to have benefits.

That said, there are two common misperceptions that consumers need to be aware of in order to use dietary supplements wisely. First, although dietary supplements look similar to over the counter drug products in their packaging, and they may be located in stores next to OTC products, they are not subject to the same standards as drug products.

Second, simply because dietary supplements are touted as having natural ingredients, that does not mean that they have a natural effect on the body or that they are safe and effective for all uses. Ephedra has been shown to contain various chemical stimulants that act on the body like a shot of adrenaline.

The concentrations of these stimulants in a product depend upon many factors, such as the particular type of plant used in the production methods, especially the extent to which concentrated ephedra is used.

Ephedrine and pseudoephedrine are used in certain over-the-counter and prescription drugs, where they have been regulated as drugs, and demonstrated to be safe and effective for the labeled short term or occasional use.

In addition, ephedra has been used in herbal medicine preparation for thousands of years. In recent years, ephedra has been marketed widely for weight control and for enhancing athletic performance, and in some cases is being used as an illicit street drug alternative.

Many of these products contain other stimulants, such as caffeine, that have synergistic effects, and that scientifically would be expected to increase the potential for adverse effects. A number of adverse effects, including dizziness, nausea, vomiting, anxiety, high blood pressure, rapid heart rate, can unquestionably be caused by ephedra use.

Other less common, but more serious adverse events, including heart attacks, strokes, seizure, and death, have been reported to the FDA in association with the use of ephedra-containing products.

The agency's history in reviewing ephedra under DSHEA is substantial. In summary, the agency has long-standing concerns about potential risks associated with ephedra. Based on adverse event re-

ports and other consumer complaints, in the mid-1990's the agency proposed restricting access to ephedra.

This regulatory action was largely halted after criticism that the statute required the FDA to prove that ephedra presented a significant or unreasonable risk as labeled, and that a limited number of spontaneous adverse event reports alone were insufficient to support the proposed regulatory action.

When I arrived at the FDA last year the agency was engaged in several efforts to compile the most comprehensive scientific information possible about the risks and benefits of ephedra products.

Specifically, the agency had been able to gain access to significant additional adverse event information from manufacturers of ephedra. Although mandatory reports on adverse events is a major way in which the FDA gets information about potential problems involving drugs, nothing in the law requires dietary supplement manufacturers to provide such reports to us.

These adverse event reports were provided to the Rand Corporation under a contract with the National Institutes of Health as part of a comprehensive review of adverse events, as well as all other recent evidence on ephedra.

In addition, the agency had taken steps to gain access to existing clinical data from trials that had been conducted by Drs. Boozer and Daly at the request of specific manufacturers.

These clinical studies included the longest follow-up of patients or people taking ephedra, versus alternative treatment for weight loss in a controlled trial setting, and have been cited by some as evidence of ephedra safety.

Yet, under the law, the FDA had no power to obtain access to this important underlying data. Successfully gaining access to both the adverse event reports and the Boozer-Daly study, gives the agency a complete basis for evaluating ephedra's safety. That is, as a complete basis as is possible under or using available evidence to evaluate ephedra's safety.

On February 28, Secretary Tommy Thompson and I announced the conclusions from that comprehensive Rand review of the evidence on ephedra's risks and benefits. In evaluating the potential benefits of ephedra, the Rand Report found only limited evidence of effect of short term weight loss and minimal evidence of any effect on sports performance enhancement.

Also, Rand concluded that ephedra is associated with higher risks of mild to moderate side effects, especially when taken with other stimulants. Moreover, in the review of some 15,000 adverse event reports, two deaths were revealed, four heart attacks, nine strokes, one seizure, and five psychiatric cases, in which the records appeared thorough, and no other contributing factors were identified.

Rand called such cases sentinel events, and the study recognized that such case studies are a limited form of scientific evidence. The study also identified other such events potentially associated with ephedra, in which other factors may have contributed to the adverse events, or in which the records were inadequate.

In addition to the results of the Rand review, agency experts are currently evaluating data from the Boozer-Daly studies and the agency requested that outside experts also review that data.

As you may be aware these outside experts raised some concerns about the limitations of the study design for demonstrating ephedra's safety. In addition the expert reviewers pointed out concerns about the significant increase in blood pressure and heart rate in the ephedra group relative to the controls.

The agency review of these data is ongoing. In February when we announced the results of the Rand review and announced a re-opening for public comment on FDA's previous proposed regulation of ephedra in light of all of the additional evidence on its risks and benefits, we also proposed a strong warning label for any ephedra product that continues to be marketed.

These changes would make it clear to users via a black box warning on the front of the product, as well as additional product labeling, that serious adverse events and death have been reported after using ephedra and that the risk of adverse events are particularly high with strenuous exercise, and with the use of stimulants, including caffeine, and for people with a range of common health problems like heart disease and high blood pressure.

In addition the agency sought comments on whether ephedra should be considered adulterated in the event it presents a significant or unreasonable risk of injury at the recommended level of use on the label, the DSHEA standard for which there has yet to be an application.

We also discussed the need for additional relevant evidence on ephedra's safety based on the FDA's more extensive pharmaceutical regulation of synthetic ephedrine, which is identical to the main active ingredient in ephedra, and which has not been associated with the same volume of adverse events.

We are currently in the process of analyzing over 16,000 public comments that we received earlier this year. Because we are engaged in a deliberative process in our rulemaking, I can't discuss the specifics of that process or the anticipated outcome.

I do want to be clear about one thing. We are working expeditiously to take effective action in the interests of public health based on the best possible scientific evidence, and the fullest authorities available to us under the law.

Along with this regulatory process for ephedra, in recent months the FDA has dramatically increased its enforcement actions against ephedra products making false or misleading claims.

These actions, many of which have been undertaken in collaboration with the Federal Trade Commission, are having a real impact on the marketing of ephedra. At the core of FDA's effort is its commitment to enhance the legitimate manufacture, sale, and use of dietary supplements while maintaining a zero tolerance for fraudulent product claims and other illegal practices.

Achieving these goals relies on many strategies, including cooperation and coordination with other Federal, State and international law enforcement agencies, in protecting consumers against unapproved and potentially harmful products.

First, based on the conclusion of the Rand review, warning letters were sent to over two dozen ephedra manufacturers challenging them to remove unproven claims, with a particular focus on athletic performance enhancement claims.

As a result of FDA's enforcement actions, all but one of these products are no longer being marketed for sports use, and we are pursuing further enforcement action against the one remaining firm.

We are also supporting FTC's actions against overblown and unsubstantiated weight loss claims in ephedra advertising. Since performance enhancement and weight loss are the two principal ways in which ephedra has been marketed, the impact of these enforcement actions has been substantial.

On March 31 of this year the agency also initiated additional enforcement actions against eight manufacturers of products that were being marketed as street drug alternatives. These products which were labeled to affect psychological states are not intended to supplement the diet.

They are intended for recreational purposes, to get high. We will continue to vigorously enforce the law against those who would market ephedra or other supplements as alternatives to street drugs.

As the tragic deaths of Baltimore Oriole's pitching prospect Steve Bechler, and 16 year old high school football player Sean Riggins, have reminded all of us that the use of ephedra even for weight loss continues to raise important concerns about safety.

Our science-based safety concerns stem from both the pharmacologic mechanism of action of ephedra and accumulating evidence of potentially serious adverse events with the use of ephedra-containing products.

Mr. Chairman, as you know, many of the sports leagues that testified today regarding their concerns about the use of ephedra share the concerns that we have. Many of these leagues have already taken action to restrict ephedra use by their players.

I applaud them for doing so. These actions are prudent. Although we have not yet completed the procedures required under our statute for determining whether ephedra presents a significant or unreasonable risk for the general population, we have repeatedly made clear that we have a high level of concern about the risks of ephedra for persons engaged in strenuous exercise.

Let me repeat. Ephedra acts like an adrenalin boost, stressing the heart, raising blood pressure, and increasing metabolism, so its risks are potentially much more serious for competitive athletes than for the general population.

Moreover the stimulating effects of ephedra may mask the signs of fatigue, causing even the most well-conditioned athletes to push beyond their physical limits. These clear risks, coupled with the fact that ephedra has no proven benefit for sports performance, means that ephedra should not be used by people engaged in strenuous exercise and that includes professional athletes.

Mr. Chairman, thank you for inviting me to participate in your joint hearing, and I would be happy after Mr. Beales' opening statements to take any questions that you may have.

[The prepared statement of Hon. Mark B. McClellan follows:]

PREPARED STATEMENT OF MARK B. MCCLELLAN, COMMISSIONER, FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Thank you, Mr. Chairman for this opportunity testify before your Subcommittees at this joint hearing on ephedrine alkaloid containing dietary supplements.

BACKGROUND ON REGULATION OF DIETARY SUPPLEMENTS

More than half of the population of the United States uses "dietary supplements." The Dietary Supplement Health and Education Act of 1994 (DSHEA) (P.L. 103-417) set up a unique regulatory framework in an attempt to strike the right balance between providing consumers access to dietary supplements that they may choose to use to help maintain and improve their health, and giving FDA the necessary regulatory authority to take action against supplements or supplement ingredients that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded. Although dietary supplements are generally regulated as foods, there are special statutory provisions and implementing regulations for dietary supplements that differ in some respects from those covering "conventional" foods. Moreover, the regulatory requirements for dietary supplements also differ from those that apply to drug products (prescription and over-the-counter).

Congress defined the term "dietary supplement" as a product that, among other things, is ingested, is intended to supplement the diet, is labeled as a dietary supplement, is not represented as a conventional food or as a sole item of a meal or the diet, and contains a "dietary ingredient." The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites, constituents, extracts, concentrates, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. DSHEA placed dietary supplements in a special sub-category under the general umbrella of "foods," but products that meet the drug definition are subject to regulation as drugs.

LABELING OF DIETARY SUPPLEMENTS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA's implementing regulations, the label of a dietary supplement must bear a statement of identity (product name) that identifies the product as a dietary supplement; nutrition information in the form of a Supplement Facts panel; a list of any ingredients not listed in the Supplement Facts panel; the name and address of the manufacturer, packer, or distributor; and the net quantity of contents. In addition, if the labeling includes a claim to affect the structure or function of the body, a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease, the product must also bear a disclaimer stating that FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, mitigate, or prevent any disease.

Products containing ephedrine alkaloids have unusual features and present complex regulatory issues. If the product is a botanical, it may meet the definition of a dietary supplement regulated under DSHEA. On the other hand, if it contains synthetic ephedrine, that ingredient and other synthetic ephedrine alkaloids (including pseudoephedrine) are regulated as drugs, which are only marketed for indications where safety and effectiveness have been demonstrated. Synthetic ephedrine and pseudoephedrine are available as components of various over-the-counter and some prescription drug products for treating allergies, asthma, nasal congestion, and related upper respiratory symptoms. None of these drug products include other ephedrine alkaloids, caffeine, or other stimulants that may interact with their effects. Synthetic ephedrine drug products are subject to stringent manufacturing, labeling, and dosing requirements. There are no synthetic ephedrine drug products approved for long-term use. Some dietary supplements have been found to contain synthetic ephedrine and FDA has taken enforcement action against their use. Nevertheless, synthetic ephedrine poses serious law enforcement and public health challenges, which are beyond the scope of this testimony.

ADVERSE EVENT REPORTING

DSHEA's regulatory framework is primarily a postmarket program like the bulk of food regulation. Thus, as with most foods, there is no requirement for manufacturers to provide evidence of product safety to FDA prior to marketing ephedra-containing dietary supplements. In contrast, drug regulation involves an extensive pre-

market evaluation of safety and effectiveness with explicit standards of evidence. This evidence provides a basis to guide not only approval decisions but also conditions of use to manage benefits and risks. In addition, there are post-market reporting requirements for drugs to support product safety monitoring. These requirements do not exist for dietary supplements.

As a result, voluntary adverse event reports (AERs) are the primary means FDA has for identifying potential safety problems with dietary supplements. Under DSHEA, FDA must rely on AERs as a major component of its post-market regulatory surveillance efforts under DSHEA. Also, unlike drug regulation, FDA cannot compel reporting of adverse events by dietary supplement manufacturers.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has recently put in place the CFSAN Adverse Event Reporting System (CAERS) to monitor adverse event reports on food, cosmetics and dietary supplement products. CAERS includes a comprehensive single computerized system that captures and analyzes all reports of consumer complaints and adverse events related to CFSAN-regulated products. This state-of-the-art system started collecting reports after June 15, 2003, and combines all existing CFSAN adverse event-reporting systems and logs reports into one portal within CFSAN.

DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS

A number of plant genera, including ephedra, are known to contain ephedrine alkaloids. Ma huang is a common name given to Chinese Ephedra, which is used in traditional Chinese medicine. Ephedra has been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine and norpseudoephedrine, as well as various tannins and related chemicals. The concentrations of these alkaloids depend upon many factors, such as the species, parts of the plant used, time of harvest, growing location, and production methods. Ephedrine and pseudoephedrine are used in some over-the-counter and prescription drugs, where they have been demonstrated to be safe and effective for the labeled use. Many of these stimulants have known, and potentially serious, side effects. While ephedra has been used in herbal medicine preparations for thousands of years, in recent years ephedra has been sold primarily in dietary supplement products for weight control, as well as in products promoted to boost energy levels or to enhance athletic performance. Some ephedra-containing products have been marketed as alternatives to illicit street drugs. Ephedra-containing products often contain other stimulants, such as caffeine, that may have synergistic effects and increase the potential for adverse effects.

A number of adverse effects associated with ephedrine alkaloid-containing dietary supplements have been reported to FDA. These include elevated blood pressure, rapid heartbeat, nerve damage, muscle injury, and psychosis and memory loss. More serious effects have also been reported, including heart attack, stroke, seizure and death.

As the tragic deaths of the Baltimore Orioles' pitching prospect Steve Bechler and of Sean Riggins, the sixteen year old from Illinois have reminded us, use of ephedra, particularly in sports, raises serious concerns about safety and has long posed difficult issues for health care professionals, regulators, and for consumers. These concerns stem from both the mechanism of action of ephedrine alkaloids on the sympathetic nervous system, and accumulating evidence of potentially serious adverse events after use of ephedra-containing products.

While there has been considerable debate about the safety and effectiveness of dietary supplements like ephedra, as well as the most effective approach to regulating them, one thing is clear: Although dietary supplements are regulated as foods and not drugs, the consumer should not assume they are always safe to use. "Natural" does not necessarily mean safe. In particular, botanical and herbal products may have active ingredients with pharmacologic properties similar to, or in the case of ephedra identical to, drug products.

USE OF EPHEDRA BY ATHLETES

I want to take this opportunity to applaud the National Football League, National Collegiate Athletic Association, and the International Olympic Committee for banning the use of ephedra by their players. Although FDA is reviewing ephedrine alkaloids under DSHEA to assess the safety concerns, FDA has particular concerns about the use of ephedra by persons engaged in strenuous exercise. A recent study by RAND, discussed in more detail below, concluded that ephedra has minimal if any proven benefit for enhancing sports performance. Yet ephedra acts like an adrenaline boost, stressing the heart, raising blood pressure, and increasing metabolism. Moreover, the stimulating effects of ephedra may mask the signs of fatigue,

causing even the most well conditioned athletes to push beyond their physical limits. Thus, ephedra's risks are potentially much more serious for competitive athletes than for the general population. As FDA has said before, ephedra should not be used by people who engage in strenuous activity.

Because of the special risks of ephedra use in athletes, I believe that the sports leagues that have acted to restrict ephedra use are making a prudent decision. Even as the Agency evaluates the safety of ephedra use in the population more generally, including its use for weight loss, I have clearly and repeatedly indicated that ephedra poses special risks in the context of sports performance with little or no identified benefit for athletes.

FDA'S RULEMAKING ON EPHEDRINE ALKALOIDS

Right now, the Agency's professional, scientific and legal staffs are working hard to address the extraordinary challenges presented by these products. The regulatory actions in process now have several major components. Earlier this year, the Agency published a *Federal Register* notice seeking comment on proposed warning label for ephedra-containing dietary supplements. These changes would make it clear to users, via a black-box warning on the front of the product, as well as additional information elsewhere in the product labeling, that serious adverse events and death have been reported after using ephedra, and that risks of adverse events are particularly high with strenuous exercise and/or use of stimulants including caffeine. In addition, the Agency reopened the comment period on its 1997 proposed rule on dietary supplements containing ephedrine alkaloids. There is now considerably more evidence available on ephedra's risks and benefits than when the proposed rule was published. In its recent *Federal Register* notice, FDA announced that it was seeking comments from health professionals, the supplement industry, and the general public on any additional data on ephedra's safety, so that we can acquire the most complete picture possible of the product's potential risks, as a basis for appropriate further regulatory action.

Our *Federal Register* announcement also sought comments on whether, in light of current information, FDA should determine that dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling or under ordinary conditions of use if the labeling is silent. In FDA's view, "unreasonable risk" implies a risk-benefit calculus. Such a calculus should examine the best available scientific evidence and take it into account in assessing whether the product's known or suspected risks outweigh its known or suspected benefits. The "sentinel" events identified by RAND, coupled with the adverse event information we have collected at the Agency and our knowledge of ephedra's pharmacology and mechanism of action, have all raised serious concerns about whether ephedra use poses an unreasonable risk.

By undertaking these regulatory actions and seeking public comments on these issues, our intent is to give DSHEA the meaning in practice that many of its supporters say it should have, by clarifying that public health authorities can use the standard in the law to determine whether a product poses unreasonable, albeit uncertain, safety risks and then take appropriate regulatory or enforcement action. We are establishing an up-to-date public record for further, legally sustainable actions based on the latest scientific evidence. We are currently in the process of analyzing the over 16,000 public comments we received earlier this summer. We are in the final stages of our deliberative review related to finalizing our rule, so I cannot discuss the specifics of that process or the anticipated outcome. However, I want to emphasize that we are committed to moving forward expeditiously to make a determination that is well grounded in all available scientific evidence and that is protective of the public health in accordance with DSHEA.

While we are undertaking these regulatory procedures, under my leadership, the Agency has dramatically increased its enforcement actions against ephedrine alkaloids and other dietary supplement products making false or misleading claims. These actions, many of which have been undertaken in collaboration with the Federal Trade Commission (FTC), are having an impact on the marketing of dietary supplements in general and ephedra in particular.

ENFORCEMENT ACTIONS

At the core of FDA's enforcement efforts is our commitment to enhance the legitimate manufacture, sale, and use of dietary supplements while enforcing the law aggressively against fraudulent product claims and other illegal practices. Achieving these goals relies on a number of strategies, including cooperation and coordination with other Federal, state, and international law enforcement agencies in protecting

consumers against unapproved and potentially harmful products offered by Internet outlets, some of which are based abroad.

With a mutual goal of consumer protection, FDA and FTC formed a Dietary Supplement Enforcement Group to closely coordinate their enforcement efforts against health care fraud. In addition, FDA and FTC chair an interagency health fraud steering committee that meets regularly to coordinate activity on these issues. The workgroup currently includes Federal agencies in the U.S. and Canada. Mexico has been invited to join the group. As part of its effort to curb Internet health fraud, FDA has conducted several “surfs” to identify fraudulent marketing of health care products over the Internet. These actions were carried out in partnership with the FTC and other law enforcement and public health authorities in the United States and abroad.

SPORTS USES OF EPHEDRA

On February 28, 2003, based on the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary supplements enhance athletic performance. The actions were primarily a result of the Agency’s surveillance of the firms’ websites. Fourteen of the firms responded to the warning letters by discontinuing the product or the claim. The remaining twelve firms were inspected by FDA. Of those twelve inspected firms, all but one either discontinued the product or the objectionable claims. Investigation for consideration of regulatory action against the remaining firm is ongoing. Since performance enhancement was one of the two principal ways in which ephedra has been marketed, the impact of these warning letters has been substantial. As a result of FDA’s enforcement actions, all but one of these products are no longer being marketed for sports enhancement.

Street Drug Alternatives

In September 2002, FDA became aware of the tragic death of Sean Riggins, the 16-year-old high school football player who had taken the product, Yellow Jackets. One source of the product was found to be a distributor in the Netherlands, which promoted the product on the Internet as an alternative to street drugs. The product was manufactured by NVE Pharmaceuticals in New Jersey.

Yellow Jackets capsules and Black Beauties capsules, another NVE product at the time, were both “street” terms for controlled substances, and are sold as herbal street drug alternatives. These products are labeled to contain ephedra extract and other herbal ingredients, including kola nut extract, a source of caffeine. Their sale as a substitute for controlled substances is illegal. FDA issued a Cyber Letter to Mr. Xoch Linnebank, Sjamaan Internet Department, The Netherlands, on October 4, 2002, regarding the sale of Yellow Jackets into the United States and placed the company’s products on import alert on October 7, 2002.

On October 8, 2002, FDA attempted to inspect NVE Pharmaceuticals, the manufacturer of Yellow Jackets and Black Beauties. NVE refused to allow the inspection and on October 11, FDA and the U.S. Marshal’s Service returned to NVE under a limited administrative inspection warrant. Although NVE refused to provide access to batch records and complaints during the October inspection, FDA obtained sufficient evidence to support an additional warrant. In January 2003, FDA and the U.S. Marshal’s Service returned to NVE under a comprehensive inspection warrant and obtained both records and complaints. FDA witnessed the firm’s voluntary destruction of both “street drug-alternative” products with a retail value of between \$4 and \$5 million.

After NVE stopped marketing Yellow Jackets and Black Beauties, they began marketing Yellow Swarm and Midnight Stallion as replacement products. These products appear to be almost identical in formulation and appearance, but they no longer bear street drug names or claims—yet safety issues associated with these types of products remain.

On March 31, 2003, FDA also took new enforcement action against firms marketing street drug alternative products, some of which contained ephedra or other sources of ephedrine. FDA sent warning letters to eight firms, again based primarily on an investigation of the firms’ websites. The investigation revealed that the firms sold products for “recreational” purposes with claims to produce such effects as euphoria, a “high” or hallucinations. As with Yellow Jackets and Black Beauties, these street drug alternatives are not dietary supplements under the legal definition, because they are not intended to supplement the diet. These eight letters went to manufacturers of products that contain the drugs ephedrine or norephedrine hydrochloride labeled as dietary supplements for use in weight loss, suppression of appetite and enhanced libido. The majority of the firms stopped selling these products

or removed the street drug alternative claims for these products. We are currently working to assure that all of the firms are brought into full compliance.

DIETARY SUPPLEMENT GOOD MANUFACTURING PRACTICES

Another important arm of FDA's regulatory and surveillance activities to help ensure the safety of dietary supplement products is improving product quality and consistency. DSHEA gave FDA the authority to promulgate regulations for dietary supplement good manufacturing practices (GMPs).

Examples of product quality problems the GMPs will help prevent are: super-potent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, glass, and lead), color variation, tablet size or size variation, under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling.

On March 7, 2003, FDA announced proposed rules to establish GMPs and labeling standards for dietary supplements. FDA's proposed rule, if adopted as proposed, would establish GMPs to help reduce risks associated with adulterated or mis-branded dietary supplement products. FDA is soliciting comments from the public and industry on this proposal. Written comments will be received until August 11, 2003.

The proposed rule would:

- Establish industry-wide standards necessary to ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition.
- Include requirements on the design and construction of physical plants that facilitate maintenance, cleaning, and proper manufacturing operations, for quality control procedures, for testing final product or incoming and in process materials, for handling consumer complaints, and for maintaining records.
- Apply to all firms that manufacture, package, or hold dietary ingredients or dietary supplements, including those involved with testing, quality control, packaging and labeling, and distributing them. The proposed regulations also would apply to both domestic firms and foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements for distribution into the U.S.

FDA EFFORTS TO OBTAIN SCIENTIFIC DATA

In order to acquire the best available scientific data to support its regulatory decisions relating to ephedra, the Agency has undertaken numerous credible and appropriate steps to gain access to information, in the form of adverse event information, clinical studies, and other scientific reviews that could be helpful in evaluating the safety concerns identified by AERs associated with dietary supplements containing ephedrine alkaloids. These successful efforts have put the Agency in a better position to make meaningful science-based decisions about these products. In particular, FDA has sought unredacted complaints from Metabolife as well as the raw data from the six-month Boozer Daly study that was conducted at the request of the makers of dietary supplements containing ephedra.

On February 28, 2003, Secretary Tommy Thompson and I held a press conference and announced the conclusions from the RAND study, commissioned by the National Institutes of Health, which reviewed recent evidence on the risks and benefits of ephedra and ephedrine based on the adverse events reports provided by Metabolife. In evaluating potential benefits of ephedra, the RAND report found only limited evidence of an effect of ephedra on short-term weight loss, and minimal evidence of an effect on performance enhancement in certain physical activities. Also, the RAND study concluded that ephedra is associated with higher risks of mild to moderate side effects such as heart palpitations, psychiatric and upper gastrointestinal effects, and symptoms of autonomic hyperactivity such as tremor and insomnia, especially when it is taken with other stimulants. Moreover, its review of some 16,000 adverse event reports revealed two deaths, four heart attacks, nine strokes, one seizure, and five psychiatric cases involving ephedra in which the records appeared thorough and no other contributing factors were identified. RAND called such cases "sentinel events," because they may indicate a safety problem but do not prove that ephedra caused the adverse event. The study recognized that such case studies are a limited form of scientific evidence. The study also identified other adverse events potentially associated with ephedra, in which other factors may have contributed to the adverse events or in which records were inadequate.

The RAND review, along with the data provided to the Agency by Drs. Boozer and Daly from their controlled clinical study of ephedra use are being reviewed by the Agency and its outside experts, along with the adverse event information the Agency has received in its own CAERS. All three of FDA's outside reviewers of the Boozer

er Daly weight loss study have raised serious concerns about that study's ability to prove the safety of dietary supplements containing ephedra.

At this time, we have amassed a significant data set and conducted substantial analyses on ephedrine alkaloids. This data set includes AERs from FDA's Medwatch and from Metabolife as well as detailed assessments by Agency experts and outside experts at RAND that have identified ephedra as an ingredient of particular concern. But as the General Accounting Office and the Rand report have noted, AERs alone in this context are sentinel events indicative of a potential safety problem, but are not enough alone to make an empirical, scientific determination with a high degree of statistical confidence that ephedra causes serious adverse events. In addition, our careful review of the Boozer Daly study and underlying data have raised additional significant concerns about the empirical effects of ephedra. At this point, we are in the final stages of our deliberative review related to finalizing our rule, so while I cannot get into the specifics of that process or the anticipated outcome, I want to emphasize that we are moving forward as expeditiously as possible to make a determination that is well grounded in the scientific evidence we have and that is protective of the public health in accordance with DSHEA. Meanwhile, under my leadership the Agency will continue to use all available resources to target our limited enforcement resources on false and misleading dietary supplement claims among other top priorities.

Mr. Chairman, thank you for this opportunity to testify. I am happy to answer your questions.

Mr. GREENWOOD. Thank you, Commissioner. Thank you very much.

Mr. Beales, you are recognized for your opening statement.

TESTIMONY OF J. HOWARD BEALES III

Mr. BEALES. Thank you very much, Mr. Chairman and members of the subcommittees. I am really pleased to have this opportunity to provide information about our efforts to ensure the truthfulness and accuracy of marketing for dietary supplements, including weight loss products and other supplements containing ephedra.

As you know the Commission has the authority to challenge deceptive and unsubstantiated claims made about a wide range of products, including dietary supplements. Over the past decade we filed more than 90 law enforcement actions challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements.

In December of last year, we announced a joint enforcement initiative with the FDA to attack false and unsubstantiated claims for dietary supplements. Since then, we have enjoined deceptive claims for more than a billion dollars in health care products, most of which were dietary supplements.

Three of these law enforcement actions have involved ephedra products marketed for weight loss. We have also previously challenged misleading claims for other ephedra products marketed for body building as energy boosters, and as alternatives to street drugs, such as Ecstasy.

Our enforcement efforts involving ephedra products have targeted two main concerns. First, do the ads make unqualified safety or no side effects claims. As the recent Rand report discusses, unqualified safety claims for ephedra products are clearly not supported by the evidence.

We view such claims as extremely serious violations. Second, we looked to see if the ads make exaggerated weight loss claims, like lose 70 pounds in 8 weeks, or use of a product that causes very rapid and substantial weight loss by reducing fat absorption by 76 percent.

Again, the Rand report concludes that existing scientific evidence on the efficacy of ephedra supplements for weight loss supports only a modest claim of maybe a half-a-pound per week for up to 4 to 6 months.

In those cases that involve unsubstantiated safety claims our orders have required strong disclosure warnings about safety risks in future advertising and in labeling. I want to emphasize that in all of our dietary supplement cases, and particularly in cases raising safety concerns, we worked closely with the FDA and received excellent support from them.

The FDA has both the expertise and the principal statutory authority to oversee the safety of dietary supplements. We view our activities on supplement safety as playing an important supporting role to FDA's more comprehensive efforts to ensure the safety of diet supplements.

Although we have always worked closely with the FDA staff, since last December, we expanded our cooperation within the area of nutrition and health. The results of our efforts include the first two dietary supplement cases that were subject to simultaneous FTC and FDA enforcement actions.

In conclusion, I would like to thank the subcommittee for focusing attention on this important consumer health issue, and for giving the Federal Trade Commission an opportunity to discuss its role.

We look forward to working with the subcommittee on initiatives concerning our dietary supplement programs, and our activities involving weight loss product marketing, and I look forward to answering your questions.

[The prepared statement of J. Howard Beales III follows:]

PREPARED STATEMENT OF J. HOWARD BEALES, III, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the Subcommittees, I am Howard Beales, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission").¹ The Commission is pleased to have this opportunity to testify about our efforts to ensure the truthfulness and accuracy of marketing for dietary supplements, including weight loss products and other supplements containing the herbal ingredient, ephedra. I will discuss the Commission's mission and our latest activities in this area.

The mission of the Federal Trade Commission is to prevent unfair competition and to protect consumers from unfair or deceptive acts or practices in the marketplace. As part of this mission, the Commission has a longstanding and active program to combat fraudulent and deceptive advertising claims about the benefits or safety of health-related products, including dietary supplements.² The dietary supplement industry encompasses a broad range of products, from vitamins and minerals to herbals and hormones, and represents a substantial segment of the consumer healthcare market. Industry sales for 2001 were estimated to be \$17.7 billion.³

Some dietary supplement products offer the potential for real health benefits to consumers. Unfortunately, unfounded or exaggerated claims in the marketplace are proliferating. As the level of deceptive claims has expanded, however, so too have

¹ The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

² Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce," and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. §§45, 52.

³ *Supplement Business Report 2002*, Nutrition Bus. J., §2 (2002)

our enforcement actions. Since December 2002, the Commission has targeted deceptive claims for more than \$1 billion⁴ in health care products, a majority of which were dietary supplements.

This testimony will provide an overview of our enforcement efforts and other activities to combat deception in the supplement marketplace, including our efforts in the weight loss area. It then will focus on our specific efforts to challenge deceptive safety and efficacy claims in the marketing of supplements containing ephedra.

THE FTC'S LAW ENFORCEMENT ACTIONS AGAINST MISLEADING DIETARY SUPPLEMENT ADS

Challenging misleading or unsubstantiated claims in the advertising of health care products, and particularly dietary supplements, is a priority of the FTC's consumer protection agenda. The Commission has filed more than ninety law enforcement actions over the past decade challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements.⁵ In this year alone, the Commission has filed or settled fifteen cases challenging claims for various supplement products, including three cases that specifically challenged safety and efficacy claims for ephedra.⁶ The Commission focuses its enforcement priorities on claims for products with unproven benefits or that present significant safety concerns for consumers, and on false and unsubstantiated claims for products purported to treat or cure serious diseases.

The Commission's enforcement actions seek to stop deceptive advertising and obtain meaningful relief for consumers. In addition to obtaining cease and desist orders, in appropriate cases, the Commission secures substantial monetary relief for consumer redress or disgorgement of profits.⁷ Further, when the marketing of a supplement involves misleading or unsubstantiated safety claims, the Commission requires that strong warning statements be placed in labeling and advertising.⁸

WEIGHT LOSS ADVERTISING REPORT

As the Subcommittees are aware, ephedra often has been marketed as an aid to weight loss. Consumers spend billions of dollars on products that purport to promote weight loss.⁹ In September 2002, the staff of the Federal Trade Commission released the *Report on Weight-Loss Advertising: An Analysis of Current Trends* ("Weight Loss Advertising Report").¹⁰ The Report analyzed claims from 300 advertisements disseminated during 2001 and concluded that the use of false or misleading claims in weight-loss advertising is widespread. Nearly 40% of the 300 ads made at least one representation that was almost certainly false. An additional 15% of the ads made at least one representation that was very likely to be false, or, at the very least, to lack substantiation.

A comparison of these ads with a sample from 1992 revealed a much higher frequency of questionable claims and marketing techniques in 2001 compared to a dec-

⁴This represents the total sales for products the Commission challenged in seventeen actions since December 2002.

⁵See, e.g., *FTC v. A. Glenn Braswell, et al.*, Civ. Action No. CV 03-3700 DT (PJWx) (C.D. Cal. filed May 27, 2003) (complaint for permanent injunction and other equitable relief); *FTC v. Enforma Natural Prod., Inc.*, No. 00-4376JSL (Cwx) (C.D. Cal. Apr. 25, 2000) (stipulated final judgment with \$10 million in consumer redress); *FTC v. Slim Down Solution, LLC*, No. 03-80051-CIV-PAINE (S.D. Fla. filed Jan. 24, 2003) (complaint for permanent injunction and other equitable relief); *FTC v. KCD Inc.*, 123 F.T.C. 1535 (1997) (consent order). A complete list of the Commission's dietary supplement cases is available at <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietadvertisingcases.pdf>>.

⁶*FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (D.D.C. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *FTC v. USA Pharmacal Sales, Inc.*, Civ. No. 8:03-CV-1366-T-23EAJ (M.D. Fla. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *U.S. v. Michael S. Levey*, Civ. No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002) (complaint challenging no side effects and weight loss claims for a supplement containing ephedra).

⁷See, e.g., *FTC v. Enforma Natural Prods., Inc.*, 04376JSL (CWx) (C.D. Cal. April 25, 2000) (stipulated final order including \$10 million in consumer redress); *FTC v. Slim America, Inc.*, 97-6072-CIV-Ferguson (S.D. Fla. June 30, 1999) (final judgment for permanent injunction and damages, including \$8.3 million in consumer redress).

⁸See, e.g., *FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (D.D.C. July 1, 2003).

⁹MARKETDATA ENTERPRISES, INC., THE U.S. WEIGHT LOSS & DIET CONTROL MARKET 6 (2002). Marketdata estimated that the total U.S. weight-loss market for 2001 was \$37.1 billion and growing at a rate of 6 to 7 % a year.

¹⁰Copies of the Weight Loss Advertising Report can be found at <<http://www3.ftc.gov/bcp/reports/weightloss.pdf>>.

ade ago. For example, ads in the 2001 sample were much more likely to promise substantial, rapid and permanent weight loss, often without any diet or exercise. Furthermore, two-thirds of the products promoted in 2001 were dietary supplements, representing a major shift from 1992 when meal replacement products were the most promoted category.¹¹

Of the 300 advertisements sampled for the Weight Loss Advertising Report, twenty-three, or about 8%, identified ephedra, ephedrine or Ma Huang as an ingredient. Of these, eleven made safety claims, and seven included a specific health warning about ephedra's potential adverse effects. Given that 60% of the sampled ads that made safety claims did not identify ingredients at all, these numbers almost certainly understate the prevalence of ephedra product advertising.

PUBLIC WORKSHOP ON WEIGHT LOSS PRODUCTS

In light of the Weight Loss Advertising Report's findings, the Commission held a public workshop in November 2002 to explore the impact of deceptive weight loss product ads on the public health and identify new approaches to fighting the proliferation of misleading claims.¹² Government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of the media participated in the day-long event. A report on the results of the workshop will be released later this year.

In addition, our staff has been meeting with members of the media, and other interested parties to encourage them to weed out facially false weight loss advertising before it runs.¹³ We are exploring what assistance the Commission can provide to the media in this effort.

COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION

Under a longstanding liaison agreement,¹⁴ the FTC has primary responsibility for the advertising of foods, cosmetics, devices, and over-the-counter drugs while the Food and Drug Administration ("FDA") has primary responsibility for the labeling of those products and advertising of prescription drugs. Our dietary supplement activities follow the same model. We coordinate our enforcement efforts closely with the FDA. Our enforcement actions targeting false or unsubstantiated supplement safety claims play an important supporting role to the FDA's more comprehensive efforts to ensure the safety of supplement products.¹⁵

Since December 2002, the FTC and FDA have intensified the level of their cooperation. The Commission staff actively participated in the work of the FDA's Consumer Health Information for Better Nutrition Initiative to better provide reliable information to consumers about important developments in nutrition and health, and to step up enforcement actions against deceptive claims for dietary supplements and other health products. On July 10, 2003, the FTC and the FDA announced the results of the first six months of coordinated enforcement efforts, including joint actions against widely advertised supplements claiming cures for serious diseases.¹⁶

RECENT DEVELOPMENTS INVOLVING THE MARKETING OF EPHEDRA PRODUCTS

The FTC has challenged marketers of dietary supplements containing ephedra when they make claims that the products cause substantial weight loss or are safe or have no side effects. The recently released Department of Health and Human Services report, *Ephedra and Ephedrine for Weight Loss and Athletic Performance*

¹¹ Weight Loss Advertising Report at 21.

¹² *Advertising of Weight Loss Products*, 67 Fed. Reg. 59,289 (2002).

¹³ See, e.g., Remarks of FTC Chairman Timothy J. Muris to the Cable Television Advertising Bureau (Feb. 11, 2003), DO THE RIGHT THING (APOLOGIES TO SPIKE LEE), <<http://www.ftc.gov/speeches/muris/030211rightthing.htm>>; Remarks By Commissioner Sheila F. Anthony Before The Food and Drug Law Institute 45th Annual Educational Conference (Apr. 16, 2002), COMBATING DECEPTION IN DIETARY SUPPLEMENT ADVERTISING, <<http://www.ftc.gov/speeches/anthony/dssp2.htm>>; Remarks of Commissioner Orson Swindle to the Aggressive Advertising and the Law Conference (Apr. 28, 2003), COMBATING DECEPTIVE ADVERTISING—THE ROLE OF ADVERTISERS, THE MEDIA, AND THE FTC, <<http://www.ftc.gov/speeches/swindle/030428aggressive.htm>>.

¹⁴ See Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶9,859.01 (1971).

¹⁵ The Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994), requires a manufacturer of a dietary supplement to have substantiation for any structure/function claims it makes so that the claim is truthful and not misleading. DSHEA also authorizes the FDA to proceed against a supplement that presents a significant or unreasonable risk of illness or injury.

¹⁶ See *FTC v. Kevin Trudeau, et al.*, Civ. Action No. 03 C 904 (N.D. Ill. filed June 9, 2003) (complaint for permanent injunction and other equitable relief); *FTC v. Seasilver USA, Inc., et al.*, Civ. Action No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003) (complaint for injunctive and other equitable relief).

Enhancement: Clinical Efficacy and Side Effects ("Rand Report"), concluded that the existing scientific evidence on the efficacy for weight loss of ephedra-containing dietary supplements supports only "modest" weight loss of about ½ pound per week for up to four to six months.¹⁷ Furthermore, in contrast to assurances in ads that ephedra is safe or without side effects, the Rand Report concluded that "the use of ephedrine and/or the use of ephedra or ephedrine plus caffeine is associated with two to three times the risk of nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations."¹⁸ Moreover, the Rand Report noted that adverse event reports for the supplement contain a sufficient number of cases of death, myocardial infarction, cerebrovascular accident, seizure, or serious psychiatric illness in young adults to warrant a case-control study to determine whether ephedra consumption may be causally related to these serious adverse events.¹⁹

Since 1997, the FTC has brought seven enforcement actions challenging efficacy and safety/no side effects claims for supplements containing ephedra.²⁰ These cases have challenged claims for ephedra products marketed for weight loss, body-building and energy supplements, and as alternatives to street drugs such as Ecstasy. In these cases, we have challenged allegedly deceptive efficacy and safety claims as false or unsubstantiated. Our orders have required a strong disclosure warning about safety risks in future advertising and labeling.²¹

For example, the Commission filed two additional settlements with companies that made allegedly deceptive safety and weight loss claims for ephedra supplements. In one case, the Commission's complaint challenged, as false or unsubstantiated, dramatic claims of substantial and safe weight loss for users of a product called Berry Trim Plus.²² Ads for this product made claims such as "Teacher Loses 70 lbs. In Only 8 Weeks Easily!" and "100% safe!" In the second case, the FTC challenged as false or unsubstantiated claims for an ephedra product called Meta Biological.²³ Ads for this product claimed that "you lose pounds and inches SAFE-LY... without counting calories, without depriving yourself of tasty, delicious foods."

In these two cases, we alleged that there is not sufficient evidence to show that these products work as advertised or are safe for everybody. In both cases, the defendants agreed to an order that bans them from making certain false weight loss claims, requires substantiation for other weight loss claims, prohibits safety claims

¹⁷ AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPT' OF HEALTH AND HUMAN SERV., EPHEDRA AND EPHEDRINE FOR WEIGHT LOSS AND ATHLETIC PERFORMANCE ENHANCEMENT: CLINICAL EFFICACY AND SIDE EFFECTS ("RAND REPORT") 219 (2003).

¹⁸ *Id.* at 9.

¹⁹ RAND REPORT at 223. In addition, at the request of the FDA, researchers conducted an independent review of 140 reports of adverse events related to the use of dietary supplements containing ephedra alkaloids that were submitted to the FDA between June 1, 1997, and March 31, 1999. The results of the review were published in the *New England Journal of Medicine* in December 2000. The authors found that "thirty-one percent of cases were considered to be definitely or probably related to the use of supplements containing ephedra alkaloids, and 31 percent were deemed to be possibly related." The authors also found that, "(o)f the sudden catastrophic cerebrovascular and cardiovascular events, 11 occurred in previously healthy persons." Christine A. Haller & Neal L. Benowitz, *Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids*, 343 *NEW ENG. J. MED.* 1833-38 (2000). Other recent studies raise further concerns about the safety of ephedra. See Stephen Bent, et al., *The Relative Safety of Ephedra Compared with Other Herbal Products*, 138 *ANNALS OF INTERNAL MED.* 468-71 (2003) (Although ephedra products make up less than 1% of all dietary supplement sales, they account for 64% of adverse events associated with dietary supplements); L.B. Morgenstern, et al., *Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke*, 60 *NEUROLOGY* 132-35 (2003) (The rate of hemorrhagic strokes among ephedra users was statistically significantly higher than among non-users for people taking doses above thirty-two milligrams a day).

²⁰ In addition to the three cases listed *supra* note 6, at 3, and discussed in detail below, these actions include *Robert C. and Lisa M. Spencer, dba Aaron Co.*, FTC Docket No. C-4019 (July 30, 2001) (consent order involving safety claims for an energy product containing ephedra); *FTC v. AST Nutritional Concepts and Research, Inc.*, Civ. No. 99-WY-2197 (D. Col. May 4, 2000) (stipulated final order involving safety claims for body-building supplements containing both androstenedione and ephedra); *FTC v. Mex-RX US, Inc.*, Civ. No. SACV99-1407-DOC(ANX) (C.D. Cal. Nov. 24, 1999) (stipulated final order involving safety claims for body-building supplements containing both androstenedione and ephedra); *Global World Media Corp.*, 124 F.T.C. 426 (1997) (consent order involving street drug alternatives containing ephedra).

²¹ In addition, the Commission's order against Global World Media for its marketing of ephedra as a street drug alternative includes a prohibition against marketing in media targeted at young audiences. Specifically, the consent order prohibits disseminating any ads for "Herbal Ecstasy" and similar products containing ephedra in any media where more than 50% of the audience is under 21 years of age. See *Global World Media*, 124 F.T.C. at 446.

²² *FTC v. Health Laboratories of North America*, Civ. No. 03 1457 (D.D.C. July 1, 2003).

²³ *FTC v. USA Pharmacal Sales, Inc.*, Civ. No. 8:03-CV-1366-T-23EAJ (M.D. Fla. July 1, 2003).

for ephedra without reliable scientific evidence, and requires the defendants to include a strong warning about safety risks in future advertising and labeling.²⁴ Both orders also require the defendants to pay consumer redress.

In addition, last month, the U.S. Department of Justice, on the Commission's behalf, sued Michael Levey, Gary Ballen, and their companies.²⁵ The complaint alleges that these defendants deceptively claim that their ephedra products, "Zymax" and "MillinexES," cause fast, substantial weight loss without dieting or exercise or side effects.²⁶ The Commission has asked the court to enjoin the defendants from making similar deceptive claims in the future and order the defendants to pay consumer redress. In addition, because the challenged claims violate an earlier Commission order, we have asked the court to award civil penalties. The case remains in litigation.

Deceptive advertising and unsubstantiated claims about the health benefits or safety of dietary supplements put consumers' health at risk. The Commission will continue to take law enforcement action against marketers who make safety and efficacy claims for any product without reliable scientific evidence to back up the claims.

CONCLUSION

The Commission thanks the Subcommittees for focusing attention on this important consumer health issue and for giving the Federal Trade Commission an opportunity to discuss its role. The Commission looks forward to working with the Subcommittees on our initiatives involving the marketing of dietary supplements, and, in particular, products containing ephedra.

Mr. GREENWOOD. Thank you, Mr. Beales, for your testimony, and let me begin my questioning with Commissioner McClellan. Given your statement today that ephedra poses special risks with little or no benefit for athletes, isn't it now medically irresponsible for baseball teams to continue to allow its players to use ephedra?

Mr. MCCLELLAN. I think professional sports leagues, like baseball teams, should take action to restrict ephedra use by their players. The health evidence that I just discussed, and significant evidence of risk for people who are engaged in strenuous exercise, versus the lack of evidence of any real benefit, is a medical basis for action on this important issue.

Mr. GREENWOOD. The ephedra industry's argument is that these products have been safely used in China for 5,000 years. But isn't that really not applicable since the FDA's inspectors of ephedra firms in China, and the FDA's analysis of ephedra alkaloids doesn't seem to show any connection whatsoever between U.S. ephedra supplements and traditional Chinese medicine?

Mr. MCCLELLAN. The way that ephedra has historically been used in Chinese medicines are in relatively low amounts and low concentrations for such health problems as breathing disorders.

²⁴ For example, the Commission orders in *Health Labs of North America* and *USA Pharmacal Sales* require the following warning in print advertising:

WARNING: This product contains ephedra or ephedrine alkaloids, which can have dangerous effects on the central nervous system and heart and can result in serious injury. Risk of injury can increase with dose, and may even include heart attack, stroke, seizure, or death. Consult a health care provider prior to use if you have high blood pressure, heart or thyroid disease, diabetes, difficulty urinating, prostate enlargement, or glaucoma, or are using any prescription drug. Do not use if you are taking a MAO inhibitor or any allergy, asthma, or cold medication containing ephedrine, pseudoephedrine, or phenylpropanolamine. Discontinue use if you experience rapid heart beat, chest pain, severe headache, shortness of breath, dizziness, sleeplessness, or nausea. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it. The product may not be safe for your developing baby.

We are carefully reviewing the Rand Report and monitoring the ongoing FDA proposed rule-making on ephedra to see if their findings would warrant any modification in the safety warnings required by future Commission orders.

²⁵ *U.S. v. Michael S. Levey*, Civ. No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002).

²⁶ The Commission also charged the defendants with making similar deceptive weight loss claims for a non-ephedra supplement called "Serotril."

The way that ephedra is marketed in the United States for performance enhancement and weight loss, and the like, is a very different kind of product. The manufacturing practices that we observed in China involved such steps as concentrating the ephedra crystals for use in the dietary supplement products that are sold in the U.S. market. That is not a part of Chinese traditional medicine practice at all.

Mr. GREENWOOD. But that does not in and of itself violate DSHEA though does it? And the letter of the law?

Mr. McCLELLAN. No, it does not, and as long as it is a natural product that is a supplement to the diet and is marketed that way, it is within the letter of the law, that's right. But it is not part of traditional Chinese medicine.

Mr. GREENWOOD. So then to take action, you would have to go beyond the fact that it is a dietary supplement and contains dietary ingredients, and you would have to get to the unreasonable risk of illness or injury?

Mr. McCLELLAN. That's right. As long as it is a natural substance, and we have taken action against a number of manufacturers of supplements that were including synthetic ephedrin which is the main active ingredient in ephedra, in their products.

And that is a chemically identical substance, and when it is produced through synthetic means, we regulate it as a drug, and we can take enforcement actions that way. But for the naturally produced substances that are used in many of the dietary supplements today, it is a different standard under DSHEA.

Mr. GREENWOOD. And which is in my mind part of the weakness with DSHEA, because you can get the same molecule in a couple of ways, and it can have profound physiological impacts on people, and the fact that it was extracted from a plant, versus synthesized, seems ultimately to be irrelevant.

Now, the manufacturers of these products, not only do they take the ma huang plant and crystalize it, and concentrate it, but then they add caffeine, and then they add other stimulants.

And we learned yesterday that they added, for instance, a bovine extract, or a bovine complex. And I asked the manufacturer or the gentleman who was in charge of manufacturing for Metabolife what bovine complex was, and he didn't know, which I found fairly astounding, that the guy who is in charge of it doesn't even know what it is.

And we learned this morning that as I suspected yesterday that it is extracted from bull testicles, cow ovaries, bull prostate glands. When they began to add these kinds of ingredients does that not in any way kick them out of the DSHEA protections?

Mr. McCLELLAN. They are naturally occurring ingredients and it does fit within this broad and diverse definition of products covered in DSHEA. So the onus would remain on us to prove that they present an unreasonable risk if they are used in these products.

Mr. GREENWOOD. A January 2003 article, in *Neurology*, on ephedra and hemorrhagic strokes, seems to say that there is a threefold risk for daily use exceeding 32 milligrams. The vast majority of supplements suggests dosages that exceed 32 milligrams on a daily basis.

For instance, Metabolife 356 claims 12 milligrams of ephedra per caplet, and recommends 1 to 2 caplets, 2 to 3 times a day. Taking the upper end, this would result in 72 milligrams per day.

In light of this article's findings would you recommend that supplement companies lower the suggested dosing information below 32 milligrams immediately on their labels?

Mr. MCCLELLAN. The issue of what dosing, if any, presents or does not present an unreasonable risk is exactly the kind of issue that we are considering in our ongoing regulatory process, and we will have a lot more to say about that soon.

Today, what I can say about that study is that it is an example of the kind of evidence that we have available now that we have included in our public record as a basis for the actions that the FDA intends to take to protect the public health with respect to ephedra use.

That study was an add-on to a very well designed case control study looking at the risks of another compound, phenylpropanolamine, which was found to be associated, especially at higher doses, with a risk of hemorrhagic stroke.

And that compound has now been removed from products available over the counter in the United States. So that is a piece of information that we are using in our regulatory process, and we will be considering that, along with all the other evidence that has come along, as a basis for further action on potential restrictions on——

Mr. GREENWOOD. Let me ask this final question then on my time with regard to further evidence. What additional evidence would the FDA require to ban dietary supplements containing ephedra alkaloids?

Mr. MCCLELLAN. Well, we have tried very hard in recent months to get all the evidence there is. Before when the FDA tried to proceed down this regulatory path, we got a lot of criticism for relying only on adverse event reports, and they were only a fraction of the adverse event reports that were out there.

Since that time we have obtained each and every adverse event report that has been known to be available somewhere, in a company or elsewhere. We have obtained the best available study data for our use in evaluating what the safety risks are. We have looked at the Rand report and all of the studies that have been published in recent months, like the Neurology study that you mentioned, as well as other studies.

For example, the Annals of Internal Medicine. We have all of the evidence that exists, and it is about the best possible data that we could use for proceeding to make a decision about the appropriate marketing, if any, of this product. And definitely a ban on ephedra use is something that is in the range of options that we are considering.

Mr. GREENWOOD. And when do you think you will be finished making that decision?

Mr. MCCLELLAN. As soon as possible. We have an enormous number of comments to go through. We want to make sure that we are going to take action that will stand up in court. This is a legal standard, the unreasonable risk as labeled standard, and is one that has not been tested before, and we want to get it right.

So we are going to do it as quickly as we can, but we are going to get it right.

Mr. GREENWOOD. The chair thanks the gentleman and the chair thanks my colleagues for the indulgence, and the Chair recognizes the gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman. Following up on the chairman's question, you said that you have all of the evidence. Are you familiar with the testimony this committee heard yesterday about the fact—a lot of people have been criticizing the adverse event reports because they are saying that they are not scientifically—you know, we can't prove that the person had the heart attack because of the ephedra, et cetera. Did you hear that? Did you hear that kind of criticism that you are hearing?

Mr. MCCLELLAN. That kind of criticism is not fresh with yesterday's testimony. We have had an advisory committee review this, and the Rand review noted that it was very difficult to prove a causal relationship based on adverse event data alone.

Ms. DEGETTE. Right. But then the other thing we heard is the few studies that have been conducted scientifically on ephedra have limited their sample size to healthy adults without any of the counter-indications that they may have.

Mr. MCCLELLAN. And relatively small sample sizes, too. So that you may not be able to pick up, or you may not have the statistical power to pick up serious adverse events that occur in fewer than, say, 1 in 10, or 1 in 20 people.

Ms. DEGETTE. Right. And the experts also said that we may not be able to conduct—we may not be able to get a board to certify a study that would have these patients with heart problems or other kinds of problems because it would be unethical to conduct those kinds of studies, correct?

Mr. MCCLELLAN. That's correct.

Ms. DEGETTE. And so it seems to me that you all are in kind of a box, because I have a few studies with very small sample sizes, but even if you did larger studies, you could not conduct them on the types of people that ephedra is a severe health risk to.

Isn't that part of the problem because we have this DSHEA process, which is a process wholly separate from, say, a drug approval process?

Mr. MCCLELLAN. You are right. The drug approval process requires much more extensive clinical testing up front under well monitored conditions to identify whether there are important adverse effects.

And some of the weight control drugs that we have approved recently, for example, studies have involved several thousand patients under carefully monitored conditions for long periods of time.

That is not going to happen here. That's why we have tried our best to get access to all possible data with a bearing on the risk and benefits of ephedra, and that is what we are going to have to use as a basis for our regulatory actions.

Ms. DEGETTE. Is it your agency's view that it would be helpful to have additional legislative authority to be able to more easily ban these dietary supplements that really do pose a severe health risk to people?

Mr. MCCLELLAN. Well, Secretary Thompson pointed out again yesterday that there are burdens placed on the agency by the fact that we bear the burden of proof, and we can't compel the production of many of the types of data that we would like to have in order to demonstrate effectiveness.

Ms. DEGETTE. Is the agency prepared right now to work with this committee to begin to write some legislation to tighten up those standards so that you can more easily and quickly respond when you find a severe health risk like the risk that is clearly posed by ephedra?

Mr. MCCLELLAN. Congressman, I truly appreciate your offer to help us do our job.

Ms. DEGETTE. No, I am asking you to help us.

Mr. MCCLELLAN. Where we are focused right now is on testing whether the DSHEA law can work in this case. The unreasonable risk standard has not been tested in court before.

Ms. DEGETTE. I'm sorry, I don't have very much time.

Mr. MCCLELLAN. I understand.

Ms. DEGETTE. Would you all be willing to work with us to help us rewrite the law to clarify, in addition to the work that you are doing right now?

Mr. MCCLELLAN. Well, we are always happy to provide technical support on issues within FDA jurisdiction. At this time, if you are asking whether on behalf of the administration that I am advocating a change in the DSHEA law, I am not doing that right now.

What I am saying is that we are trying very hard to see if the law can be made to work in this area.

Ms. DEGETTE. Well, yesterday, Secretary Thompson said that, quote, and I am quoting from a wire service story, that Congress should rewrite a law that will back dietary supplement regulations and require manufacturers to acknowledge potential health effects.

So I would assume that since Secretary Thompson is saying this to the press, you might have some experts over there who could help us rewrite this law.

Mr. MCCLELLAN. And we do provide or we will provide technical assistance on any legislative matter that the committee wants to pursue and thinks is important to pursue.

Ms. DEGETTE. My question is do you believe that the FDA currently has the legal authority to control or even to ban ephedra?

Mr. MCCLELLAN. That is why we are conducting this process right now. We are using the best evidence possible and we have put forth earlier this year a possible interpretation of what the unreasonable risk standard means, and we are saying that it doesn't mean that you have to prove conclusively with 95 percent or higher statistical certainty that there is a causal relationship.

Ms. DEGETTE. So you do believe that the FDA has the legal authority right now under current law to control or even ban it?

Mr. MCCLELLAN. We are trying to do the best job possible under current law to do the right thing for the public.

Ms. DEGETTE. I'm sorry, but that is an easy question. Do you think you have the legal authority to ban it?

Mr. MCCLELLAN. I don't mean to be difficult, Congresswoman. It is an easy question. It is a hard topic. No one has ever tested this

law in court, and tested what the unreasonable risk standard means.

Clearly, we are not going to be able to demonstrate conclusively because of all of the reasons that you mentioned whether or not there is a casual relationship between ephedra and certain risks.

Ms. DEGETTE. So your answer—

Mr. MCCLELLAN. You have to use the best possible evidence, along with what we think is the right interpretation of the statute, to reach a conclusion for the public health, and that is what we are trying to do now.

Ms. DEGETTE. So your answer is that you don't know if you have the authority to ban it?

Mr. MCCLELLAN. I would say that we are doing the best job possible to take appropriate action for the public health under the law. I can't tell you whether or not we are going to ban it.

Ms. DEGETTE. I have got to say that if you don't know what your authority is, what is the use of looking at all of the evidence to see what you can do?

Mr. MCCLELLAN. The law has never been tested in court. We are going to do the best job possible.

Ms. DEGETTE. So you are going to do nothing?

Mr. MCCLELLAN. No, absolutely. I mean, if you look at what we have done over the last 6 months—

Mr. GREENWOOD. Would the gentlelady yield?

Ms. DEGETTE. I would be delighted.

Mr. GREENWOOD. If I may, I think what I hear the Commissioner saying is that this is a multi-step process. Process No. 1, or the first step of the process is to collect enough material, enough data, which they are deeply engaged in, to determine whether the standard, the risk standard in the current statute, is met.

And if they conclude that the risk standard is met, then they would take action, and that action would be certainly challenged in court. I also assume that if the FDA comes back and concludes that the statute is sufficiently unclear, that they can't be certain based on the evidence available to them that the risk threshold is met and would stand up in court, that that would be a very appropriate time to come to us and suggest that they need additional legislative clarity.

But they already of course know what authority they have. They are in the process of seeing whether the fact pattern in this case is sufficient to utilize that authority.

Ms. DEGETTE. Well, reclaiming my time, Mr. Chairman—

Mr. GREENWOOD. Such as it is.

Ms. DEGETTE. Reclaiming my time, as a former litigator, I understand the uncertainty of trying to litigate in court, especially when you have new standards that are set under a new law that had been untested.

But what happens is that Congress gave the agency the authority to determine whether they thought a drug presented an unreasonable risk, and if the agency felt that given all the evidence that there was an unreasonable risk, I believe it was Congress' intent that the agency should have the ability to either control, or even ban, a dietary supplement.

Mr. GREENWOOD. That's right.

Ms. DEGETTE. And at that time it would be left up to the court's interpretation.

Mr. GREENWOOD. That's right.

Ms. DEGETTE. But if the agency doesn't even know if it has that authority right now, I don't have any idea how they can think that they could ever get enough evidence to make that decision, and that is my frustration.

Mr. MCCLELLAN. I think I am agreeing with your statement. I'm sorry if I am not communicating clearly.

Ms. DEGETTE. Thank you.

Mr. MCCLELLAN. We certainly intend to take the action that is appropriate for the public health based on our assessment of the risks and benefits of this product when we have got all the evidence.

Ms. DEGETTE. And that could include banning the product.

Mr. MCCLELLAN. And that could include banning the product.

Ms. DEGETTE. Thank you.

Mr. GREENWOOD. The gentleman from Michigan, Mr. Stupak, is recognized for inquiry.

Mr. STUPAK. Thank you, Mr. Chairman. Is there any benefit to ephedra?

Mr. MCCLELLAN. Congressman Stupak, it has been shown to result in some at least short to medium term weight loss, and that Boozer-Daly study that was mentioned, which is the longest best done study out there, and that only included about 60 or so patients in each arm, and only followed the patients for 6 months, there was about a 6 pound difference in weight loss between the group that got ephedra and the group that got the placebo treatment. On the other hand—

Mr. STUPAK. So it should be marketed then for the benefit if it is a weight loss benefit then, right?

Mr. MCCLELLAN. If the benefits of weight loss outweigh any other risks associated with the product, that would be an appropriate way to market the product, or the appropriate way to label it. What we are concerned about is that there may be some risk that go along with that benefit for weight loss.

Mr. STUPAK. You mentioned the Boozer data, Dr. Boozer's data, and I would like to explore that a little bit, because I was surprised in your testimony when you indicated that you have had successful efforts to gain information.

And you go on to say such as adverse events, clinical study data, and other scientific reviews that could be helpful in evaluating ephedrin alkaloids. And I am surprised to hear you say that, because in an answer to one of the questions from Ms. DeGette, you said that Secretary Thompson, that you could not compel documents or studies, and data. That was in response to Ms. DeGette.

But earlier this year, and last year, some of us on the committee tried to give the FDA subpoena power so that you can compel studies and get your data, and you rejected that. So if you had subpoena power would it help you with getting Dr. Boozer's studies?

Mr. MCCLELLAN. Well, certainly more power to compel the production of adverse event reports or studies would have made it possible for us to get that.

Mr. STUPAK. So subpoena power would be helpful then?

Mr. MCCLELLAN. It would have reduced the time and effort required to get the data.

Mr. STUPAK. Because when you get to Metabolife here, and their adverse events reports, you have had great difficulty in getting that from them, correct?

Mr. MCCLELLAN. That's correct.

Mr. STUPAK. And have you ever received unredacted adverse event reports from Metabolife or from anyone else?

Mr. MCCLELLAN. We just received unredacted adverse event reports from Metabolife this week, I believe. Yes, Monday.

Mr. STUPAK. Monday?

Mr. MCCLELLAN. Monday.

Mr. STUPAK. Okay. So Metabolife was Monday that you got that information unredacted?

Mr. MCCLELLAN. That's right. We asked for that information quite some time ago.

Mr. STUPAK. And didn't the FDA's chief counsel oppose the Justice Department's efforts to obtain the adverse event data?

Mr. MCCLELLAN. Well, that was before my time at the FDA.

Mr. STUPAK. Right.

Mr. MCCLELLAN. But my understanding is that what our legal counsels advised us to do was to pursue a criminal action that ended up giving us access to the redacted adverse event reports, and that worked. That got us the adverse event reports.

Mr. STUPAK. You just got it Monday.

Mr. MCCLELLAN. No, the unredacted—let me be clear. The unredacted adverse event reports came in Monday. The redacted adverse events reports we received last year after initiating a criminal action against Metabolife.

Mr. STUPAK. Right. But then in order to get the redacted ones after you initiate criminal action, you negotiated with the Ephedra Education Council did you not to get those reports?

Mr. MCCLELLAN. Well, we certainly asked Metabolife and people associated with them for access to the unredacted information. I would like to say that we were able to get a lot of use out of the redacted information.

What ended up—what was supposed to be redacted from those files was just personal information, and not information on the medical treatments, or dosing, or anything like that.

Mr. STUPAK. A lot of us are pretty suspicious when you deal with a group that is providing—the Ephedra Education Council, they whitewashed the reports and they give them to you, and how do you know you are getting—

Mr. MCCLELLAN. Well, that's why we are glad to have access to the unredacted data now, and we will be going through it as promptly as possible to make sure that we are not missing anything from the redacted versions.

Mr. STUPAK. The records and some of the documents that we have seen also shows that the FDA had to agree to outside reviewers who are deemed acceptable to the industry before you could even get the redacted data.

Should the FDA have to accept industry conditions about products it regulates before you receive the information?

Mr. MCCLELLAN. The FDA should not accept any conditions that would in any way impair our ability to do an unbiased, thorough, and expert review of any and all data provided to us. And I am confident that in this case we were able to get the impartial expert reviews that we needed of the data.

Mr. STUPAK. You indicated in an answer to another question, and I believe it was from Ms. DeGette again, that as you are going through this, you want to make sure that you put warnings, black box warnings, that you had talked about?

Mr. MCCLELLAN. We propose that for any product that remained on the market. We also made clear that we were considering restrictions, and maybe even a ban, on ephedra products as well. All of that is on the table in our current regulatory process.

Mr. STUPAK. Well, let's say you do the black box warning. Once you do the black box warning, will you require the manufacturers to hold their products from the market then until they put the black box warning on?

Mr. MCCLELLAN. Yes. Usually when we impose any warning like that, there is a little bit of time for compliance so that products that are on the shelves don't necessarily have to be pulled off.

But it could be a matter of a few months, or a month, or something like that. That would be something that we would consider if and when we made such a requirement.

Mr. STUPAK. So 90 days would be reasonable then?

Mr. MCCLELLAN. Potentially. I could not give you an exact timeframe. It would depend on such issues as the costs of changing the label and the production practices, and how urgently we felt the action needed to be taken.

Mr. STUPAK. Has the FDA approved the labeling on these tablets now or the containers that they come in?

Mr. MCCLELLAN. Generally, we don't. However, if the product doesn't have a label that complies with the guidance that we think is necessary, we can declare the product misbranded, and then we can seize it, and we have done that before for dietary supplements, and we will do it again if they don't comply with what we think is the right thing to do.

Mr. STUPAK. So with these dietary supplements, we are going to have to change the DSHEA law in order to give you that power?

Mr. MCCLELLAN. In order to get the labeling changed, I don't think you need to change the law.

Mr. GREENWOOD. The time for the gentleman has expired.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. GREENWOOD. The chair recognizes Chairman Stearns to inquire.

Mr. STEARNS. I thank the chairman. I have here a product, Yogi-Tea. It is a healing formula, and it has got ephedra in it, and if I am not incorrect, I think it is 3.33 milligrams of ephedra per tea bag.

And on the container, the box, it has got a huge description of the problems. For example, not to be used by individuals under an age of 18. Do not use if pregnant or nursing. Consult a physician or licensed qualified health care professional prior to use if you have a family history of heart disease, thyroid condition, high blood

pressure, diabetes, depression, or other psychiatric conditions, glaucoma.

It goes into almost everything. So it is right there. Now if a person is calling for the banning of something like ephedra, would this—let me ask both of you. Would that be included in the ban?

Mr. McCLELLAN. Let me start by saying that that tea that you are describing, and I am not familiar with that specific product, but it sounds like it is closer to a traditional kind of herbal product than the concentrated ephedra that is present in many dietary supplements that may have doses of 25 or 30 milligrams per pill or more.

Something that we are definitely considering in our regulatory review now is the dosing, and what kind of concentrations—

Mr. STEARNS. So not all ephedra is alike?

Mr. McCLELLAN. Not all ephedra is alike, in terms of concentration, and in terms of the total dosing amount per day. Tea bags certainly seem to be in a different class than a pill with concentrated ephedra in it.

Mr. STEARNS. So the constituents sometimes write to me and they say that we are worried that if the FDA steps in, then what is next. Are they going to go to all different things, whether it is cough drops, or whether it is herbs that they are using for improving their ability to protect against colds, and so forth.

And let me ask Mr. Beales now of the Federal Trade Commission. This has a lot of information on it. So would your position be that whenever ephedra is used that there should be a report of the adverse effects on the container?

Mr. BEALES. Well, I think if there is a warning on the container as you described, then there is clearly no unqualified safety claim. They have indicated what the risks are. I think if they tried to make an unqualified safety claim in the advertising, that also has to be substantiated.

It is not enough to just have the warning on the label. What we would look at in any event is do they have enough evidence to substantiate whatever claims they are making about the performance of the product and what it will do for the consumer.

Mr. STEARNS. This has a lot of promises here on it. It promotes balance and easy breathing. It aids in countering many of the negative effects of stress, pollution, poor breathing habits, on the respiratory system. It has been used for 5,000 years to promote bronchial functions. It is beneficial to respiratory health. Used to support the body with less stress.

Now, I am assuming that all these things that they say that you would accept?

Mr. McCLELLAN. I think you will also see on that label a statement that the FDA has not evaluated those claims. One of the other features of the dietary supplement law was that for broad claims like those about how a product might affect the structure or function of the body, they must carry a disclaimer saying that the FDA has not evaluated the claims, but they are allowed under the law.

Mr. STEARNS. It says here in a box that these statements have not been evaluated by the Food and Drug Administration. The

product is not intended to diagnose, treat, cure, or prevent any disease.

Mr. MCCLELLAN. There you go.

Mr. STEARNS. That is pretty small and hard to see, but it is there.

Mr. MCCLELLAN. That's right, and that is a reflection of the provisions of the 1994 law. I would like to add here that in close collaboration with the FTC, we are thinking hard about whether there are more effective ways that we can address the legitimacy of claims about a product's impact on structure and function.

We have been aggressively enforcing the law against specific disease claims. So, for example, you don't see that product saying that it cures the common cold. But we are also exploring ways of addressing structure function claims as well, and that the enforcement actions that we took earlier this year against ephedra products that said they had an impact on sports performance and enhancement that has not been proven are an indication of that. So I think you can expect to see more from us on this.

Mr. STEARNS. Mr. Chairman, just 1 more minute to ask a question.

Mr. GREENWOOD. Without objection the additional minute will be granted to the gentleman from Florida.

Mr. STEARNS. How many enforcement actions has the FDA taken in matters involving ephedra supplements since you became Commissioner, and what were the number of FDA enforcement actions taken in the year 2001 and 2002?

Mr. MCCLELLAN. Mr. Chairman, I became Commissioner in mid-November of last year, and since that time we have issued 34 warning letters against ephedra-containing products. Most of those were for claims about enhancing sports performance, and as I mentioned in my opening statement, virtually all of those are gone from the market now.

As a result a number of the letters were also about ephedra-containing products that were being marketed as street drug alternatives, claiming that they basically helped to get high. That is not a dietary supplement rule, and so we are making some real progress in preventing those kinds of claims as well.

We have also engaged in consent decree and have supervised the voluntary destruction of a product that—of an ephedra-containing product worth over \$4 million. In looking back at the history in 2002, altogether we issued a total of 8 warning letters and 2 internet letters. So, 10 letters.

And in 2001, we had no warning letters issued to impact products on the market, and just one product seizure. So, this is something where we really are trying to step up, and I didn't get a chance to thank you at the beginning of this hearing.

But Mr. Chairman, I really appreciate you bringing attention to this issue, particularly as it relates to sports performance. There has been some real misuse of that product there, and it is important to bring that to the public's attention.

Mr. STEARNS. Thank you, Mr. Chair.

Mr. GREENWOOD. The gentleman's time has expired. The gentleman from California, Mr. Waxman, is recognized for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman. Dr. McClellan and Mr. Beales, please to see you.

Mr. BEALES. A pleasure to see you.

Mr. WAXMAN. You are struggling on this ephedra issue as to what evidence you need to act, and what the standard of the law is that would permit you to act. Now, we have heard testimony that there is no demonstrable health benefit from dietary supplements containing ephedra, combined with caffeine, and the reviews of the adverse event reports published in peer review journals have found ephedra probably caused heart attacks, strokes, and death.

The known pharmacological effects of ephedra alkaloids are consistent with those adverse events, making these biologically plausible, and the adverse events are consistent with the risk of stroke found with PPA, a close chemical cousin of ephedra, which has led many professional and public health organizations, including the AMA, and the American Heart Association, the American Society for Clinical, Pharmacological, and Therapeutics to call for a ban.

And most of the expert witnesses who testified here yesterday believed that ephedra poses risks so high that it should be removed from the market. Now, if that is what we are hearing, and if that is the conclusion that you also reach, isn't that enough to take a dietary supplement with this profile off the market?

And is it your argument that the standard in DSHEA is not going to permit that if you reach that conclusion?

Mr. MCCLELLAN. What I tried to be clear about is that since we have a regulatory process open now that has incorporated all of that evidence that you mentioned, evidence that was not available to us in some cases until recently, and evidence that was not available the last time the FDA had a public comment period as a basis for regulatory and enforcement action on ephedra, all of that information is going into our regulatory process now.

And so because that is open, I can't tell you exactly what we are going to do, but I can tell you that we are going to take account of all of that evidence and we are going to take the appropriate action for the public health given the full extent of our interpretation of the DSHEA law.

Mr. WAXMAN. Well, we certainly want you to make the decision, because it is a scientific matter protecting the public health, but we don't want you to be stuck with a standard that you think is too difficult to meet when you have a product that meets a profile as we have been hearing from other witnesses. And that, it seems to me and most members of this committee, should permit the FDA to take timely action against what we think from many people is a dangerous supplement. Some people are suggesting that you may say that there ought to be a 2 or 3 year study of this product and look at larger numbers of people.

That could mean that the product will stay on the market much longer. So I guess what we need from you is not the question of the evidence, because you will evaluate that. But a clear interpretation of the standard, and whether it is sufficient for you to act, or whether we need to make a different standard.

Mr. MCCLELLAN. Well, we tried to put out our interpretation of the standard earlier this year as part of a white paper that I issued, which said that we do not interpret the unreasonable risk

standard to mean that we have to prove with 95 percent certainty or more that there is a causal relationship between significant adverse events or risks, and the use of a product, in order to take action.

Rather, we think that the unreasonable risk standard means that we need to evaluate the evidence, uncertain as it is on benefits and risks, and if that evidence, even if uncertain, shows that the benefits are less than the risk, than that would be a basis for us taking action under the statute.

We put that interpretation out there earlier this year, and we got a lot of comments on that, too, as part of this process. So that is going into our regulatory decisionmaking right now. You are right that this takes longer than it would if this was a drug product, a PPA product, a phenylpropanolamine, that you mentioned was studied.

And it was a very good study that showed some significant evidence of an increased risk, and because it is regulated as a drug, we asked the manufacturer whether he wanted to do further analysis.

In fact, the manufacturer funded that study. We were able to compel that study because of our drug authorities.

Mr. WAXMAN. Well, it sounds like what you are saying to me then is that in effect that you have less of an ability to act when it comes to a dietary supplement, and that it may be harmful—

Mr. MCCLELLAN. I think it is obvious that it takes more time than it did in the case with phenylpropanolamine and being under a drug statute in this case.

Mr. WAXMAN. Many of the dietary supplement industry are trying to distance themselves from ephedra, and some have even called for the ban, and others have said that they just would not oppose a ban.

But they are in effect saying that ephedra is a special case. If ephedra is removed from the market can consumers be confident that all remaining supplements on the market are safe?

Mr. MCCLELLAN. No, the requirement again is that we have to prove that a supplement is unsafe for it to be removed from the market as long as the manufacturer asserts that their supplement is safe, and that there is not clear evidence to the contrary, then it can remain on the market.

That's why I think it is important for us to try to see how effectively we can actually implement this statute. As I said, this unreasonable risk standard has not been tested. We are going to do it and we may end up doing it in this case, and in the meantime there is no reason for consumers to believe that all the ephedra dietary supplements on the market are safe for use.

And as I mentioned in my opening statement, just because it is natural doesn't mean it is safe. These products are not subject to the same kind of drug regulation that gives people confidence that the drugs that they use are safe and effective.

Mr. WAXMAN. I understand that some companies have already removed ephedra from their products, and they substituted other ingredients. What do you know about the safety of the other ingredients?

Mr. McCLELLAN. We have seen the same reports. We know less. Some of these ingredients, such as forms of orange peel, do contain ingredients that have the same kind of adrenalin like effects on the body.

There is not as much of a profile of safety evidence on them. There is not as much of a track record of adverse events, and even fewer studies than have been done with ephedra. So there is a considerable amount of uncertainty there.

Mr. WAXMAN. Some people have suggested that you deal with the ephedra products in a different way when it comes to children, and their use by minors. You can't legally as I understand it say that it can't be sold to minors, but you could require a special warning label. Is there any evidence that label statements saying that a supplement should not be sold to minors actually prevents the use of the product by minors?

Mr. McCLELLAN. I don't know the details of that evidence off-hand. I do know that our labeling changes in general have an impact on the way the products are used, and that we would do all that we could using our educational programs and other outreach efforts to make sure that the public knows, and that people takes steps to avoid sales to minors.

But it is not an absolute requirement that is binding in law, if that is what you mean.

Mr. GREENWOOD. The gentleman's time has expired. The chair recognizes the chair of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman. Dr. McClellan, let me again go back and maybe set the stage for a few questions. One, maybe you can help me with this. What has been the number of adverse event reports that the FDA has received for ephedra?

Mr. McCLELLAN. We have got somewhere in the neighborhood of 17,000 plus adverse event reports, consumer complaints. It is a very diverse set of products that includes about 2,500 that we got reported to us through various means, and about 15,000 plus that came in from Metabolife. And not all of them are real adverse events. Some of them are just consumer complaints.

Chairman TAUZIN. Some are just complaints, but there are an awful lot of adverse events.

Mr. McCLELLAN. Right, there are a lot of adverse events in that.

Chairman TAUZIN. And how does that compare to other complaints or reports issued or received for other herbal diets or dietary supplements?

Mr. McCLELLAN. Unquestionably, ephedra counts for disproportionate share, either half or more, in the range of half or more, of the adverse event reports that we have gotten on dietary supplements.

Chairman TAUZIN. And we are told, too, that adverse events are generally under-reported to the FDA. What evidence do you have that the FDA receives reports from only a fraction of the ephedra-related adverse events.

Mr. McCLELLAN. A couple of years ago, I believe that the FDA asked the Office of the Inspector General to review how thorough our adverse event reports were.

Chairman TAUZIN. What was their estimate?

Mr. MCCLELLAN. Their conclusion was under 1 percent of the actual adverse events get reported to us through these voluntary reports.

Chairman TAUZIN. So to put it in perspective again, you have about 17,000—and not all of which are serious adverse effects, but nevertheless pretty substantial. The GAO tells you that is 1 percent of the likely problems that consumers would complain about, or experience adverse effects for.

And I also understand that it is about 15 to 1 over other dietary herbal supplements. Is that about right?

Mr. MCCLELLAN. I am not sure that it is that high. We have a lot of other adverse event reports, and in terms of significant adverse events, in the neighborhood of half or more.

Chairman TAUZIN. But it is a GAO number.

Mr. MCCLELLAN. But unquestionably a huge share of adverse event reports on dietary supplements are related to ephedra.

Chairman TAUZIN. And I want to take us back to Metabolife itself. I mean, here is a company, and Mr. Mike Ellis' corporation, where you said you received about 15,000 now reports, some adverse events, and are consumer complaints.

And my understanding for many years in conversations or in communications with the FDA deny that there were any adverse events.

Mr. MCCLELLAN. They did. They specifically denied that there were any adverse event reports in the process of our public docket on our earlier regulation.

Chairman TAUZIN. And my understanding is that the only time they finally came forward with a redacted account of these adverse events was right after the U.S. Attorney's Office out west opened up a criminal investigation; is that correct?

Mr. MCCLELLAN. Right, with our involvement.

Chairman TAUZIN. And then it was not until Monday of this week that we finally get an unredacted account of these complaints; is that correct?

Mr. MCCLELLAN. That is absolutely correct.

Chairman TAUZIN. But the evidence seems to be mounting, and you yourself indicated that there were only eight enforcement actions taken before you took office 8 months ago, and there have been 34 since, for which I want to comment you and your office.

Mr. MCCLELLAN. Thank you.

Chairman TAUZIN. But the evidence is mounting then that this is a problem that has sort of been not only swept under the rug, but conveniently hidden under the rug for a long time. Is that about right?

Mr. MCCLELLAN. Well, we have certainly tried to bring it out. I think that we have access to all the information that is out there now, but it took a long time to get it. There was a lot of stuff around.

Chairman TAUZIN. In fact, the FDA's request to Metabolife to give you an unredacted account of these some 15,000 complaints was resisted by the company, using all sort of legal complaints about what may be happening in the criminal investigation. Is that correct?

Mr. MCCLELLAN. That's correct.

Chairman TAUZIN. And only Monday do we get the unredacted records, which then tell us the sex of the complainant, and other information that might be helpful in terms of understanding what is going on out there, right?

Mr. MCCLELLAN. That's correct. We only got that information on Monday.

Chairman TAUZIN. And one further clarification. Do you have any doubt that your office has authority, given the right evidentiary findings, to take action in this case?

Mr. MCCLELLAN. We are going to take action that we think is appropriate based on the statutory standard of an unreasonable risk. So we are going to go forward with that.

Chairman TAUZIN. And what we are engaged in right now at your department is an evidentiary examination, right?

Mr. MCCLELLAN. Yes.

Chairman TAUZIN. You have to establish that there is an unsafe condition out there.

Mr. MCCLELLAN. That's right, especially since the last time the FDA tried to move forward in regulating in this area, when we only had a limited amount of adverse event information, we were severely criticized for not having enough to meet the statutory standard. Now we have got every bit of important evidence we think is out there.

Chairman TAUZIN. And given the opportunity you now have to build this evidentiary case record, and to exercise the authority you acknowledge you have, we will learn very soon whether or not your authority is adequate in this area, or we need to supplement it with additional legislation. Is that correct?

Mr. MCCLELLAN. That's correct.

Chairman TAUZIN. Give us a time line. When are we likely to learn whether your authority is adequate, or whether we need to step in as a Congressional legislative team to supplement your authority?

Mr. MCCLELLAN. Well, Mr. Chairman, I know that you would like for me to give you a specific date, and I would like to be able to give you one, but this is a difficult process, with a lot of evidence that we have to go through, and a lot of public comments.

We are working extremely hard on it, and so all I can tell you that is that there is going to be action soon, and I would expect that if we take action to significantly restrict ephedra use, then there would be a legal challenge of some sort.

So we would be finding out pretty soon after we take action, if we take action, and I want to be careful to make clear that I am not prejudging how our regulatory process is coming out.

Chairman TAUZIN. I understand, and you can't, and you shouldn't.

Mr. MCCLELLAN. But if we were to take action, I would expect that there would be a court challenge very quickly that would enable us to fine out just how well the statute works.

Chairman TAUZIN. I want to make one final comment, Mr. Chairman, that on a day in which we will be voting on the House floor, potentially to open up this Nation's drug market to an unspecified and unregulated volume of imports of drugs that may come in from anywhere in the world, that the FDA cannot certify it to be safe.

It is interesting that you should get any criticism that you are not moving fast enough on a drug or on a product rather than Congress exempted from ordinary FDA regulation and review.

I wish you well on your journey. We are anxious to hear from you as soon as you can as to whether or not you need additional authority, Doctor, because I assure you that you have heard from this panel.

We stand ready to assist you in this effort, and to assist the FTC in its efforts to make sure that advertisements of the nature of which we have seen in this investigation are carefully scrutinized to protect unsuspecting, and particularly young, people from what appears to be occurring out there, and I thank you, Mr. Chairman, and yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the chairman. The Chair recognizes Mr. Pallone, and while not a member of either of the subcommittees, we are happy to extend to him the opportunity to join us in this hearing, and recognize him for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman, and I want to apologize, because I had to attend another subcommittee hearing this morning, and I couldn't be here for anything other than to just come at the tail end here.

And I have been listening to what Mr. Tauzin said and what Ms. DeGette said in particular. My concern—and you have heard me before, and I feel like it is inappropriate to pick on you, Commissioner, because you have not been at it as long.

Mr. MCCLELLAN. Well, that's okay. It is part of the job.

Mr. PALLONE. I know, but it is 10 years now almost since DSHEA was passed, and you have not been here for that much of it. But the frustration that I have is that I was a very big supporter of putting DSHEA in place. I worked with Bill Richardson on the committee at the time.

And both the people that used dietary supplements, as well as the manufacturers, have been saying on a regular basis for the last 10 years, and every time the Secretary comes here, I always ask him the same question, which is that in my opinion you have the enforcement power under DSHEA.

We just want the regulations, the GMPs, to be put forward, and every time the Secretary—and not the current Secretary necessarily, but the previous ones, would say, okay, they are going to come out in 6 weeks, or they are going to come out in 2 months.

And finally they came out under your agency here, and so I shouldn't really be critical of you. But it just seems to me that we just face this constant situation, where we were asking for the GMPs, because that was the one way really to go about implementing DSHEA in a favorable way.

And then at the same time there were various people within the industry that were putting out their own GMP type regulations and trying to get other manufacturers to go along with it.

But of course they didn't have the enforce power to do that the way that the FDA does, and you even had some within the industry who question the authority for the GMPS, or enforcement ability to go after and just prohibit ephedra, or whatever you want to do.

And it is just very frustrating to me because I think that the longer that we take to take the enforcement action, the longer it is before the GMPs are in effect, and because they are not in effect yet, the more human cry.

Naturally there is on this committee, and I guess in the general public, well, is DSHEA working. What is happening. Is it useful. And I blame it all on the fact that the agency has taken so long to put all this into place.

And I guess my only question is what was—well, two questions. What was it the reasoning, if you can answer it, what was the reason why the FDA took so long to come out with the GMPs?

Why didn't they put an ephedra regulation in the absence of GMPs. And if you can just answer that. And how long do you think it is going to take for these other things to occur for you to take enforcement action?

Mr. MCCLELLAN. I don't know if I can give you an answer to that question. I mean, this is a complicated area, and it is a law with new standards that are different than what we do in drugs and other areas, and it is one that does present some challenges for implementation.

But let me assure you that I am going to use our fullest extent of authority under the law to implement good manufacturing practices in this industry. That's why it is one of the first things that I got done after coming into the office here, was to take enforcement actions where appropriate.

One of the main uses for which ephedra has been marketed in this country for sports performance enhancement is essentially gone as a result of our enforcement actions, and there is more coming as a result of this full evidentiary record that we have developed using the best available evidence on ephedra's benefits and risks.

So we are going to be doing everything possible under the law to protect the public health related to dietary supplements, and you have got my firm commitment on that.

Mr. PALLONE. But you seem to suggest that you have a problem with the basic standard itself that is in DSHEA, and that you are going to have a problem in enforcing any action under that standard.

Mr. MCCLELLAN. Well, let me just be clear. It does take more effort on our part to get adverse event information to compel studies to interpret evidence that is out there that may be incomplete in the dietary supplement law, compared to the drug law. But that is the way the law is set up and we are going to do our best job possible under the statute to work with it.

Mr. PALLONE. But you are not saying in any way that you can't implement that. That it is a different standard, but that it can be implemented and it can be enforced.

Mr. MCCLELLAN. Well, that is what we are trying to do right now.

Mr. PALLONE. The other question, of course, that I have is to what extent you have reviewed some of these other standards that were put out either specifically for ephedra or for the GMPs in general, and relied on those in terms of what you are putting for.

Mr. MCCLELLAN. We are intending to apply the GMP standards to all dietary supplement products, including products like

ephedra, to make sure that there are no impurities in there or anything else.

In addition, we are reviewing the unreasonable risk standard right now and the comments that we received on it, along with a review of all of the evidence on ephedra's risks and benefits, and that is going to be our basis for further action on ephedra. And you will hear from us soon on further action on ephedra.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair recognizes himself for 5 minutes, and I am going to go back to you, Mr. McClellan. Do you agree with expert testimony from yesterday's hearing that it would be unethical to study ephedra supplements in patients without medical screening.

And one of the manufacturers at least suggested that it would pay for long term or long range studies, but some of the witnesses yesterday had ethical concerns about doing that.

Mr. MCCLELLAN. Well, careful medical screening would need to be done at the outset and then careful medical screening along the way given what is known about the potential risks here.

One of the independent reviewers that we had look at the Boozer-Daly study in fact suggested that if there were to be a longer term, better study done that it might need to be done in a clinical research center. That's where you monitor people more or less continuously for potential adverse events on an ongoing basis, in addition to doing the careful screening up front. So that would present some challenges to doing such a study.

Mr. GREENWOOD. And of course that might give you some data about how people respond when under medical supervision, but the vast majority of people, or virtually 100 percent of the people who take these ephedra products, are not getting them prescribed by a doctor, and they are probably not having them suggested by a doctor, and they certainly are not being screened necessarily or anything else.

Mr. MCCLELLAN. That's right.

Mr. GREENWOOD. Would you also agree that it would be unethical to conduct long term studies on ephedra?

Mr. MCCLELLAN. Again, it certainly would be challenging. If a study was very well designed with that kind of ongoing monitoring that I mentioned, it is possible to set up some break points in the study.

So if there were evidence of significant adverse events the study could be halted. We have reviewed as part of our approval process for some weight loss drugs in recent years the protocols for some large, well done, clinically, closely monitored studies for products where we were at least potentially worried about significant adverse events.

So it could be potentially done and it would need to be done very carefully. And as you said, this is the kind of evidence that is most relevant to potentially approving a product for use as a prescription drug.

Mr. GREENWOOD. You note in your statement that, quote, our careful review of the Boozer-Daly study and underlying data have raised additional significant concerns about the empirical effects of ephedra. What are these significant concerns?

Mr. McCLELLAN. The Boozer-Daly study found, along with the weight loss that was mentioned earlier in the treatment group, a significant increase compared to placebos, in blood pressure, and heart rate of people on the medication.

This is concerning, because No. 1, higher blood pressure and heart rate in and of itself is a proven risk factor, a serious risk factor, for many serious cardiovascular diseases.

And, No. 2, normally when we test when people lose weight, we see a reduction in blood pressure, and a reduction in heart rate. That is one of the main mechanisms why we think it is so important for people to lose weight, and to reduce the cardiovascular stress on their system.

So as some of the reviewers noted, those are important reasons to be concerned about the findings in the Boozer-Daly study.

Mr. GREENWOOD. Thank you. Mr. Beales, in my opening statement, I referred to an advertisement in Men's Health. It is an advertisement for xenadrine, and what we have it—and I know that you can't see it from here, but I will describe it.

We have four young people who are apparently sticking their stomachs out as far as they can, and looking as droopy and unfit as possible in the before pictures; and then we have ostensibly the same four people, anywhere from 10 to 14 days later, completely as the terminology is used, ripped and buffed, and about as fit as one could be.

And it says that losing weight just got a whole lot easier and faster, too, thanks to revolutionary new xenadrine EFX. And it says that Darlene lost 19 pounds in 14 days; and Matt lost 15 pounds in 10 days.

Now, one of the items that came out at the hearing yesterday was that when this company, Cytodyne, runs these ads, they pay these people a few thousand dollars a piece for the before and after photographs. And I think they had them sign a statement that said, yes, they used the product.

But there is no convincing evidence that they ever took the product or took it once, or took it as directed. There is no way to substantiate any of this. Now, I realize that it is a pretty complicated thing to try to substantiate these kinds of things. They are using all kinds of advertisements.

But what is the FTC's options here in clamping down on this kind of thing, or is it really beyond the scope of your authority.

Mr. BEALES. Well, no. We brought a large number of cases that are based on claims made in testimonials. We have a set of testimonial guides that specify that even if you are describing—when you describe the experience of somebody who is giving a testimonial, it has got to be truthful. It has to actually be their experience.

And you have got to be able to substantiate the claim on its own. The testimonial itself makes a claim that this product is good for significant weight loss, and if you can't substantiate that claim with adequate scientific evidence, then that is actionable deception.

There have been problems with testimonials, and we are planning to start in the near future a review of those guides, because too many advertisers have added—and you may find it there and

you may not, but they have added fine print disclosures that say that results are not typical.

Mr. GREENWOOD. And this one certainly says in the finest of fine prints, it says used as directed and with sensible nutrition and exercise program. Results shown may not be typical. These statements have not been evaluated by the Food and Drug Administration, et cetera.

Mr. BEALES. The FDA statement is required by FDA's rules, and "the results not typical" is the result of ours. And it is something that we are concerned about, and looking at, because I don't think that kind of a disclaimer works very well.

Mr. GREENWOOD. Okay. My time has expired. The gentlelady from Colorado. Thank you.

Ms. DEGETTE. Thank you, Mr. Chairman. If we could put the slides up on the screen, please.

[Slides shown.]

Ms. DEGETTE. These are two slides of a website taken off the internet just last week, and the graphic is from the Klein-Becker USA Website, which advertises such products as Mamolin, with a little umlaut kind of thing to give it authority, that says prevent breast shrinkage due to weight loss, and strvectin-SD, the stretch mark repair cream turned anti-wrinkle phenomenon.

And here is one called Transdural emulsifying gel, Dermalin APG. Now, here is one, and this one is really frightening to me. Do you need to lose over 20 pounds. Anorex.

Then there is one, Pedialan, weight control for children. There is one that says that it is Thyroveran, provides thyroid support during dieting; and Oxydrene, increased oxygen saturation, increased endurance.

And then finally this is the culmination I guess, Testroge, increased sex drive for you and your partner. Now, here is my question to you, Mr. Beales. It looks to me like here are some products and all of these products seem to be making some pretty amazing claims just in the little phrase.

I am wondering if your agency has investigated any of these particular supplements.

Mr. BEALES. Under our statute, we can't talk about a particular non-public investigation. All of our investigations are non-public. So we can't confirm or deny that we have looked at any particular product until we have taken action.

We have been very active in looking at weight loss claims, and for a wide variety of diet supplement kinds of products, and we are particularly concerned about weight loss claims that seem particularly focused on children.

Ms. DEGETTE. Can you tell me though whether you have taken an enforcement action against Klein-Becker USA for any of their products?

Mr. BEALES. We have not taken any enforcement action, no.

Ms. DEGETTE. Is this something that you are familiar with, or have you seen this before today?

Mr. BEALES. I have not seen the ad, no.

Ms. DEGETTE. Okay. I would ask you if you could please go back and take a look at this company and their claims, because as you said in your testimony, in your written testimony and then today

in your verbal testimony, that you have been particularly concerned with dietary supplements that appear to be making claims that would be unsubstantiated, right?

Mr. BEALES. Yes, that has been very much the focus. In the weight loss area our focus has been on claims of rapid or substantial weight loss or lose weight without diet and exercise.

Ms. DEGETTE. And I think you would agree, and probably, Mr. McClellan, you also—some of the claims just on their face seem of concern, like do you need to lose over 20 pounds, or weight control for children. Would you agree with that?

Mr. MCCLELLAN. It is certainly the kind of thing that we would be happy to assist the FTC in looking at.

Ms. DEGETTE. And I would assume, Mr. Beales, that this is the kinds of things that you have been looking at without specifically commenting on this website?

Mr. BEALES. Without specifically commenting on this website, it is the kinds of claims and the kinds of issues that we have been very interested in.

Mr. GREENWOOD. Would the gentlelady yield for just 10 seconds?

Ms. DEGETTE. I would be happy to.

Mr. GREENWOOD. I just wanted to inform the gentlelady and the committee that specifically with regard to this product Pedialan, weight control for children, this committee is conducting another investigation, and we have done extensive work on that, and that will be a subject of a hearing in the fall.

Ms. DEGETTE. I am aware of that. I am looking forward to that hearing, and part of my concern, Mr. Chairman, is when you have a product called Pedialan with a little r after it, it looks just like some of the products that the FDA approved, FDA approved products that I use in my life, like Pedecolite, or other kinds of legitimate medicines for kids.

And it is bad enough when adults are taking these herbal supplements, but when we are giving them to our children, I think that is worth a whole hearing unto itself. I want to go to slide two if I may.

And slide two, and at the bottom of that slide, gentleman, where it says, BBB On-Line Reliability Program. That refers to the Better Business Bureau icon. Do you see that, gentlemen, and are you familiar with that from other enforcement?

Mr. BEALES. Yes.

Ms. DEGETTE. And to me that seems to give the impression that the Better Business Bureau is supporting this company. Isn't that the impression that it would give to you?

Mr. BEALES. Well, I think the BBB On-Line icon is fairly widely recognized. They have concerned themselves with the privacy practices of somebody who is offering merchandise on-line.

But I don't think they see it, and I don't think consumers would likely see it as an endorsement of the products, as opposed to of the way the website does business on-line.

Ms. DEGETTE. Well, I will tell you that I would see it just the opposite, and in fact when you click on the BBB link, you are taken to a screen that states, "This company is currently not active under the BBB On-Line Reliability Seal Program." So that probably might change your view.

Mr. BEALES. That is a different sort of a problem.

Ms. DEGETTE. Yes, and one that I would think your agency might want to look into. Would I be accurate?

Mr. BEALES. It is the kind of problem that we would be very interested in.

Ms. DEGETTE. We have done a lot of work in this committee on internet issues, and I think part of the problem we are seeing is profligate advertising in products like this on the internet, which is an increasing problem for your agency and other regulatory agencies.

And I would just—I think what I might ask unanimous consent to do is to follow up with some written questions to the FTC about what kinds of on-line enforcement activities they are taking, because I am sure that you have some, and I would like to know about that.

Mr. BEALES. We are very active on-line jointly with FDA, and also with international partners. We conduct surfs looking for various targets in particular areas. We are working now with Mexico, with the FDA, with Canada, to develop an international surf that will look for websites, claims on websites around the world, and then sort of parcel them out as to what country and what agency can most effectively take action to address that. We would be happy to provide more information about that because it is an important part of what we do.

Ms. DEGETTE. Mr. Chairman, I would just ask for unanimous consent that all members may have 30 days within which to submit statements or further questions.

Mr. GREENWOOD. Without objection, that will be the order. The time of the lady has expired, which is unfortunate, because we didn't get to the grow muscle while you sleep page, nor the cutting gel where you can get muscles simply by rubbing gel on your—

Ms. DEGETTE. Mr. Chairman, I thought you would be more interested in this one, that's why.

Mr. GREENWOOD. Right. I am going to go and take a nap right after the hearing and muscle up, bulk up. The gentleman from New Jersey, Mr. Pallone.

Mr. PALLONE. Mr. Chairman, I will be very quick. I know that I am not a member of the subcommittee. Could I ask to be included in Ms. DeGette's follow-up questions even though I am not a member?

Mr. GREENWOOD. Without objection.

Mr. PALLONE. Thank you. And then I just wanted to ask very quickly a follow-up to what I said before. My understanding when we talk about the GMPs versus whatever risk regulation or prohibition on ephedra you are going to have, there is no suggestion that because of action that is being taken with regard to ephedra from a regulatory point of view that that would hold up or impact what you are doing with the GMPs, and that process won't be slowed down in any way?

Mr. MCCLELLAN. No, those are two separate activities. The GMP process applies across the board to dietary supplements, and our regulatory analysis of ephedra is something that is very ephedra specific.

There is as you know a huge number of vitamins, minerals, other dietary supplement products that don't present any known safety risks, and they often have benefits. And the main purpose of GMPs is for especially that large universe to make sure that they are produced using standards that can give consumers confidence that what is on the label is what is in the product and that there are not any potentially unsafe ingredients from bad manufacturing practices.

Mr. PALLONE. So one is not going to impinge on what you are doing with the other?

Mr. MCCLELLAN. We are very busy at the FDA, but we are pursuing both of these aggressively.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. We thank our witnesses for their time and their expertise. We look forward to their continuation of this process, and I thank the gentlemen again, and the hearing is adjourned.

[Whereupon, at 1:29 p.m., the subcommittee was adjourned.]

